



AL-16-001-0113

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 02 2016

OFFICE OF CONGRESSIONAL AND  
INTERGOVERNMENTAL RELATIONS

The Honorable James M. Inhofe  
Chairman  
Committee on Environment and Public Works  
United States Senate  
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your July 12, 2016, letter and the opportunity to respond to follow-up questions for the record from the Senate Committee on Environment and Public Works June 11, 2015, hearing to consider the nomination of Thomas Burke, Ph.D. for the Assistant Administrator of the U.S. Environmental Protection Agency's Office of Research and Development. Please find our responses in the attached document.

Again, thank you for your letter. If you have further questions, please contact me, or your staff may contact Christina J. Moody in the EPA's Office of Congressional and Intergovernmental Relations at [moody.christina@epa.gov](mailto:moody.christina@epa.gov) or (202) 564-0260.

Sincerely,

A handwritten signature in black ink, appearing to read "Nichole Distefano", is positioned above the typed name.

Nichole Distefano  
Associate Administrator

Enclosure

**FOLLOW UP QUESTIONS FOR THE RECORD FOR TOM BURKE**  
**SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE**  
**JUNE 11, 2015 NOMINATION HEARING**

**Risk Assessment:** It has been EPA's long-standing practice to conduct RAs for pesticide products by balancing potential hazards of and exposures to a product against any benefits of the product. However, it appears that the Agency has recently deviated from this practice and has focused primarily on theoretical hazards that pose negligible actual risk, when exposure is taken into account, while discounting or ignoring product benefits. This shift has substantial implications for the products that EPA approved for use under its previous, science-based, reviews. It also creates vast uncertainty for stakeholders developing new products and could eventually have a chilling effect on investment in innovative products that may be even more protective of public health and the environment.

- 1. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, communicated to anyone at EPA, in general or relating to specific reviews, regarding how the Agency, or any office of the Agency, including the Office of Pesticide Programs (OPP), should take exposure into account when estimating the potential risk of a product? If yes, please provide the Committee with copies of all such communications, including emails, memoranda, presentations, and any notes of oral conversations.**

Response: ORD provides broad scientific information regarding exposure, and this work is widely cited and applied throughout the scientific community, including the agency. Ultimate decisions regarding application of methods are made at the program office level.

- 2. If confirmed as the Assistant Administrator for ORD, what recommendations would you make to EPA offices regarding how to take exposure into account when considering the potential risk of a product?**

Response: Appropriately characterizing exposure is a critical component of fully evaluating and understanding risk. If confirmed as Assistant Administrator for ORD, I would ensure that ORD continues to provide the science needed for the agency's program offices and regions to make scientifically-based decisions about exposure and exposure assessment. ORD conducts critical and cutting-edge exposure research in our National Exposure Research Laboratory. We also build on the research done by the academic community. Additionally, we also develop information on exposure factors through our Exposure Factors Program, which includes developing the EPA's Exposure Factors Handbook and Child-Specific Exposure Factors Handbook (<https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20563>). These important exposure assessment resources provide scientific information about the factors that impact a person's exposure, such as how much water is consumed or air is breathed per day, how much of certain food groups a person eats, and other factors that influence human exposure.

- 3. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, communicated to anyone at EPA, in general or relating to specific reviews, regarding how the Agency, or any office of the Agency, including the OPP, should consider product benefits when evaluating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)? If yes, please provide the Committee with copies of all such communications, including emails, memoranda, presentations, and any notes or oral conversations.**

Response: No, ORD does not communicate how the agency, or any office of the agency, including the OPP, should consider product benefits when evaluating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

- 4. If confirmed as the Assistant Administrator for ORD, what recommendations would you make to EPA offices regarding how to take product benefits into account when evaluating pesticides under FIFRA?**

Response: If confirmed, I would continue to work to advance the application of social sciences, including economic analysis, to inform the EPA decision making. However, specific decisions about the application of the scientific data are made at the program level.

**Risk Communication:** I am also concerned about the way in which EPA has conducted registration and deregistration review for pesticides where analysis of the potential hazards is maximized, while consideration of authorized exposure levels and product benefits are seemingly minimized. For instance, in March 2016, I sent a letter to EPA citing concern over the Agency's dissemination of the preliminary RA on imidacloprid. EPA's press release on the findings of the preliminary RA inappropriately suggested more hazard than what the actual findings of the assessment warranted and singled out citrus and cotton as potential threats to pollinators. The press release also failed to explain that the primary uses of imidacloprid were found to have little or no risk to pollinators and that the potential risks identified could have been easily mitigated by labeling changes.

- 1. Do you believe it is appropriate to communicate to the public about a scientific matter, such as a preliminary RA for imidacloprid, in a way that withholds information about a major finding of the scientific review, such as the finding in the preliminary RA for imidacloprid, that the primary uses of imidacloprid present little or no risk to pollinators?**

Response: I was not involved in the EPA's risk assessment for imidacloprid, nor in the communication of the findings.

**Role of Public Opinion in Science-Based Decisions:** RAs are to be purely science-based; however, EPA employees have suggested that public pressure is playing a role in the Agency's RAs and subsequent regulation of pesticides.

- 1. Have you heard of this concern?** I am aware of this concern. The EPA uses risk assessments to characterize the nature and magnitude of health risks to humans (e.g., residents, workers, recreational visitors) and ecological receptors (e.g., birds, fish, wildlife) from chemical contaminants and other stressors that may be present in the environment. This is done through guidelines and scientific processes, public pressure is not a factor used in our evaluation.
- 2. In your opinion, what is the proper role of public opinion in scientific review?**

Response: Scientific review and public opinion are two distinct aspects of risk management decision-making. Scientific review should be based upon the body of scientific evidence, strong and transparent methods, and high level scientific peer review. The application of assessments for decision making, which takes place in the EPA's Program and Regional Offices, should consider stakeholder perspectives and public opinion, including ample opportunity for public input and comment.

If risks associated with a beneficial pesticide product can be addressed through mitigation measures such as labeling, would it ever be appropriate to instead deregister or fail to register the beneficial product?

- a. If yes, please explain how that decision would be based on science
- b. If not based on science or risk, would such a decision be based on public opinion? If so, is that appropriate?

Response: The Science Advisor is not directly involved in decisions about which actions are most appropriate to take to manage and mitigate risks. These decisions are made by the Office of Chemical Safety and Pollution Prevention at the EPA.

**Procedural Safeguards:** EPA is required to comply with a number of procedural safeguards before a pesticide registration can be cancelled. However, last year EPA asked the Ninth Circuit Court of Appeals to vacate its own scientists' 2014 approval of the pesticide Enlist Duo. This marked the first time EPA has attempted to vacate a pesticide registration through court action. The court denied EPA's request, which failed to comply with a number of procedural safeguards that must be met before a pesticide registration can be cancelled.

1. Who made the decision to ask a court to vacate the registration of Enlist Duo after the product was so recently approved for use?
2. Were you a part of and did you agree with that decision? Please provide the Committee with any documents relating to your involvement in or knowledge of that decision.
3. Do you think it is appropriate for the Agency to use the courts to change a regulatory decision:
  - a. If so, under what circumstances is it appropriate for the Agency to attempt to use the courts to regulate instead of going through proper administrative processes that ensure a robust scientific review?

Response: The Science Advisor is not involved in these decisions. These decisions are made by the Office of Chemical Safety and Pollution Prevention at the EPA.

**Spurious Rulemaking:** EPA has recently issued letters that are the equivalent of a regulatory action. This type of action circumvents steps in the regulatory process required by the Administrative Procedures Act (APA). For example, in 2015 EPA's OPP sent registrants a letter notifying them of a moratorium on new uses of various neonicotinoid pesticides. In 2013 OPP mandated that registrants include pollinator statements and a graphic on certain products. In 2009 OPP launched the pyrethroid labeling initiative.

1. Do you think it is appropriate for the Agency to impose new requirements that have binding effect and legal consequences without going through notice and comment rulemaking under the APA and without complying with the Regulatory Flexibility Act? If so, how do you justify such action?
2. Are there circumstances where regulation by letter may be appropriate? If so, please describe them.
3. Do you think the public interest would be better served by reviewing such actions through the transparent and participatory rulemaking process required by the APA?

Response: The Science Advisory Board is not directly involved. Risk management and risk mitigation issues such as those described above are addressed by program offices within the Office of Policy at the EPA.

**Reliance on Epidemiology to Make Regulatory Decisions:** I am also concerned by EPA's increasing reliance on epidemiology as a basis for regulatory decisions. As an epidemiologist, you are well aware of how epidemiology can identify correlations between environmental factors and health conditions, but cannot establish a cause and effect relationship between a given factor and a given health condition. As a result, epidemiological data have a number of limitations. Epidemiology may identify associations that have no practical meaning or effect because epidemiology does not eliminate other potential causes of an observed effect. These limitations make epidemiology an inappropriate tool for regulatory decisions because a regulation that relies on epidemiology could target the wrong stressor, leaving an actual risk unidentified and wasting resources targeting the wrong exposures.

1. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, encouraged EPA offices to increase their reliance on epidemiological studies?
  - a. Please provide the Committee with copies of all communications, including emails, memoranda, presentations, and any notes of oral conversations with EPA employees regarding the use of epidemiology.
2. Given the pesticide uses registered today, how does EPA use epidemiological studies that observe effects from exposure to previously registered pesticides?
3. Do you believe it is appropriate for the Agency to increasingly rely on epidemiological studies instead of toxicological and laboratory data?

Response: When evaluating any environmental issue, it is important to consider the full body of scientific evidence. The full body of scientific evidence should be considered when assessing risk. The EPA uses many different areas of science when conducting research on or evaluating the effects of a chemical or environmental pollutant on human health. We use peer reviewed research done in the academic community and by other research organizations. These approaches include in vitro or laboratory studies, computer modeling, animal experiments, epidemiology or observational studies in humans, and occasionally controlled human exposure studies. In vitro and animal studies are generally cheaper and reduce our reliance on human studies, and they provide information about potential ways a chemical might alter biological processes. While these types of studies offer many advantages, they may not adequately predict the impact of real world exposures – such as exposures at low levels – on human health. Epidemiology studies are considered the gold standard for risk assessment and public health decision-making. They are valued over other types of information—such as traditional animal toxicology studies—for several reasons. First, they are conducted on the species of interest—the human—so we do not have to address the challenge of extrapolating from one species to another. Second, they provide information on human variability and susceptibility that can never be accomplished using animal or human clinical studies. Finally, epidemiology studies of environmental exposures examine more realistic durations of exposure (i.e., longer than those observed in experimental studies) and health effects that generally occur at lower— and more human-relevant—levels of exposure. Because of these advantages, the risk assessment community generally prefers human data over animal data and should be given greater weight in hazard characterization and dose-response assessment. However, the full body of scientific evidence must be reviewed and considered when evaluating the potential health effects of environmental pollutants.

**Transparency:** Concerns have been raised over the lack of transparency regarding an epidemiology study known as the Columbia University study, which EPA used in its draft RAs for chlorpyrifos and seven other pesticides recognized as organophosphates. In fact, there have been reports the Agency does not even have access to the data underlying the Columbia University

study. Public comments on these draft RAs objected to EPA's reliance on the Columbia University study, which EPA has seemingly ignored.

1. What steps have been taken by EPA to obtain access to the data underlying the Columbia University study? Will you commit to ensuring the Agency obtains full access to the raw data underlying this study before using the study to make any decisions?
2. Do you think it is appropriate for EPA to rely on a study that is based on data withheld from the Agency?
3. Has EPA considered establishing an independent panel of experts to review the raw data underlying the Columbia University study before continuing use of the study? If not, why?
4. In furtherance of your previous commitment to increase public access to data, will you commit to making this data publicly available?
5. Will you ensure that EPA responds to the public comments submitted on these draft RAs?

Response: I continue to be committed to improving public access to data from all research conducted and funded by the EPA.

**SAP Recommendations:** Related to the use of epidemiology studies, in 2010, EPA convened a Scientific Advisory Panel (SAP) to review its draft framework for the use of epidemiological studies. EPA said it would revise the framework based on the SAP recommendations and would release the revised version for public comment later that year. To date, EPA has not released the revised framework.

1. What is the reason for delay in releasing this revised framework?
2. What is the current status of the framework?
3. Will you provide assurances that the Agency will, in fact, complete this task of releasing a revised framework for public comment?
4. Do you think it is appropriate that the Agency relied on the draft framework to integrate epidemiology studies into the RA for chlorpyrifos before EPA completed the revised version? If so, what is your rationale?

Response: I was not involved in developing the draft framework for the use of epidemiological studies.

**Changing Scientific Conclusions:** It has come to my attention that EPA is seemingly under pressure to come to a certain conclusion on its RA for glyphosate. EPA's cancer assessment review committee (CARC) published a report that concluded glyphosate is "not likely to be carcinogenic to humans" that was subsequently removed from the website. Despite the report being clearly marked as the "final version" as of October 1, 2015, and signed by members of CARC, EPA has claimed it is not finished with the cancer review and that publication of the report was accidental. EPA also announced it is undergoing a SAP panel process to further evaluate the cancer risk for glyphosate.

1. Did you or any ORD officials participate in meetings regarding the CARC report before its accidental publication in April 2016?
2. Did you or any ORD officials express a view about the scientific conclusions of the CARC report? If so, what was that view?
  - a. Please provide the Committee with all documents from you or ORD staff expressing a view on this report.
3. Did you or any ORD official have any role in the decision to initiate a SAP panel process to further evaluate glyphosate?

- a. If so, please provide the Committee with all documents from you or ORD staff related to any request for EPA to initiate a SAP panel process to further evaluate glyphosate.
4. Do you believe this SAP panel process is necessary since CARC had finished reviewing the cancer risk of glyphosate?
5. Does ORD have a role in the SAP panel process for glyphosate? If so, please describe in detail ORD's role in the SAP panel process for glyphosate.

Response: The role of the Science Advisor is focused on advancing the scientific research and methods that are essential for protecting the environment and public health. I was briefed on the EPA risk assessment for glyphosate by the Office of Pesticide Programs in November 2015. Given the global attention paid to potential public health risks from glyphosate exposure, it is essential to consider the full available body of evidence and assure rigorous and independent scientific peer review. I agree with OPP's decision to ask their SAP to further review their assessment of glyphosate.

AL-16-001-2021



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 06 2016

OFFICE OF CONGRESSIONAL  
AND INTERGOVERNMENTAL RELATIONS

The Honorable K. Michael Conaway  
Chairman  
Committee on Agriculture  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to respond to the questions for the record following the February 11, 2016, hearing on impacts of the Environmental Protection Agency's actions on the rural economy. Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser at [kaiser.sven-erik@epa.gov](mailto:kaiser.sven-erik@epa.gov) or 202-566-2753.

Sincerely,

A handwritten signature in black ink, appearing to read "Nichole Distefano".

Nichole Distefano  
Associate Administrator

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 06 2016

OFFICE OF CONGRESSIONAL  
AND INTERGOVERNMENTAL RELATIONS

The Honorable Collin C. Peterson  
Ranking Member  
Committee on Agriculture  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Peterson:

Thank you for the opportunity to respond to the questions for the record following the February 11, 2016, hearing on impacts of the Environmental Protection Agency's actions on the rural economy. Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser at [kaiser.sven-erik@epa.gov](mailto:kaiser.sven-erik@epa.gov) or 202-566-2753.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicholè Distefano", is written over a horizontal line.

Nicholè Distefano  
Associate Administrator

Enclosure

## **SUPPLEMENTAL QUESTIONS FOR THE RECORD TO:**

**The Honorable Gina McCarthy, Administrator, U.S. Environmental Protection Agency, Washington, D.C.**

**Public Hearing on “To consider the impacts of the Environmental Protection Agency’s actions on the rural economy”  
February 11, 2016**

***Chairman K. Michael Conaway, Texas***

**Conaway 1.** The GAO report on illegal grassroots lobbying points to the tweet “I love clean water” as one of the violations. What we have failed to discuss was EPA’s use of the innovative tool “Thunderclap” to push that tweet to more viewers, around 1.8 million. In addition to twitter, EPA used Facebook and YouTube for an aggressive social media campaign for the WOTUS rule. Did EPA count responses to the social media campaign as comments in support of the rule? How many of those people actually read and understood the details of the rule?

**EPA Response:** The EPA did not count responses on social media as comments. For any statements made in the preamble of the final rule or to the public regarding the number of comments received, the EPA only counted comments submitted to the docket or sent to the dedicated email address for this rulemaking.

**Conaway 2.** The 6<sup>th</sup> Circuit Court of Appeals, in its order to temporarily stay the rule, found that the burden of the WOTUS Rule outweighed any harm to the agencies in keeping the status quo. What are your thoughts on this?

**EPA Response:** The EPA and the U.S. Army Corps of Engineers revised their longstanding definition of the term “waters of the United States” to provide the public with more consistent, predictable, and understandable regulations defining the scope of the Clean Water Act (CWA). The result is a new rule intended to be faster, easier, and cheaper to implement saving the public time and money. Delaying implementation of the Clean Water Rule prevents the agencies from providing the public with these significant improvements. The agencies are, however, fully complying with the 6<sup>th</sup> Circuit order by staying implementation of the Clean Water Rule and implementing the prior regulations consistent with the best science and the law.

**Conaway 3.** Assuming the administration will continue to keep the final rule as written, and that the rule is to be implemented, will you consider delaying implementation of the rule to provide the time necessary for the Agencies to get adequately trained and for the regulated community to understand how federal jurisdictional decisions will be made so that they can comply?

**EPA Response:** The agencies are using the time created by the stay to address questions regarding the Clean Water Rule raised by states, local governments, and the public, and

to provide agency field staff with additional training to ensure we are in the best possible position to fairly and effectively implement the rule when the stay is lifted. We will also continue to update information and respond to questions when the new rule goes into effect to provide the public with the transparency and clarity needed to make use of the new rule more timely and less costly.

**Conaway 4.** How is EPA ensuring that the new “Waters of the United States” (WOTUS) Rule is not being utilized or implemented, in light of the current nationwide stay? What actions has EPA taken to ensure that all EPA regions and staff are not using or implementing the Rule?

**EPA Response:** The EPA and the U.S. Army Corps of Engineers distributed national guidance to their field offices on the same day the 6<sup>th</sup> Circuit stay was issued directing all field staff to cease implementing the Clean Water Rule and instead resume application of the agencies’ prior regulations defining the scope of CWA jurisdiction. The agencies regularly work with their field staff to respond to questions and to ensure the stay is being implemented consistent with the court’s decision.

**Conaway 5.** Do you believe that the Army Corps is capable of executing the Clean Water Act 404 program without EPA’s involvement? Why or why not?

**EPA Response:** The EPA and the U.S. Army Corps of Engineers have worked together effectively in the implementation of the CWA section 404 program for more than 40 years since enactment of the statute in 1972. The agencies will continue to build from their experience to make future implementation of the section 404 program even more responsive to permit applicants as we work to protect human health and the environment.

**Conaway 6.** When dealing with interagency disagreements and responses to public comments during the development of the WOTUS Rule, who had the final say on what was and was not considered a “Water of the U.S.”?

**EPA Response:** Final decisions regarding the Clean Water Rule were made jointly by senior policy managers at the Department of the Army and the EPA following extensive collaboration and discussion and consistent with science and the law.

**Conaway 7.** EPA has made it a point to state that ditches are not included as jurisdictional in the final Waters of the United States rule. However, if a ditch can be classified as a tributary, and ditches are generally formed through excavation activities, could you clarify what types of ditches are truly exempt?

**EPA Response:** The agencies have stated consistently that most ditches were subject to regulation under the CWA during the 1970s, 80s, and 90s – and that actual regulation was inconsistent and unclear causing uncertainty for landowners such as farmers and ranchers. A key goal of the Clean Water Rule is to eliminate this uncertainty and make clear for landowners, for the first time, the types of ditches that are and are not covered by the CWA. An important part of the new Clean Water Rule is a list of waters, including

many types of ditches, that are always excluded from regulation under the CWA. The new rule makes clear that most ditches on farmlands, including all ditches that flow only after it rains, or ditches excavated from dry land, are never covered under the CWA. In addition, the new rule preserves all farming, ranching, and forestry exemptions, including ditch exemptions. These exemptions in federal law allow landowners to construct irrigation ditches and maintain drainage ditches, for example, without needing to get permits or approval from the government.

**Conaway 8.** Would the ditch exemption be automatically given if the business, farmer, or local government believes their ditch is exempt, or do they have to prove the ditch is exempt? Will they have to ask for the exemption?

**EPA Response:** The agencies wrote the Clean Water Rule to make it clear and understandable. The rule does not change the longstanding application of the section 404(f) exemptions. The public, for example, is not required to obtain confirmation or approval from the government that an exemption applies. The agencies are available at no cost, however, to answer questions regarding jurisdiction, and the U.S. Army Corps of Engineers can provide landowners with written jurisdictional determinations regarding the status of ditches on their property.

**Conaway 9.** What actions have the Agency taken to ensure the Clean Water Act's prior converted cropland exemption is being preserved?

**EPA Response:** The Prior Converted Cropland (PCC) exclusion was written into the agencies' CWA regulations in 1993 to provide the public with certainty regarding the jurisdictional status of these wetlands. This regulatory exclusion was not changed by the Clean Water Rule, and the preamble to the final rule makes clear that there will be no change in the implementation of the exclusion as the Clean Water Rule is put into effect. The public can be certain the PCC exclusion will continue to be implemented as it has been since 1993.

**Conaway 10.** What actions have the Agency taken to ensure the Clean Water Act exemptions for normal farming activities under Section 404(f) are being preserved?

**EPA Response:** The agencies issued regulations following enactment of the CWA section 404(f) exemptions in 1978 and these regulations were not changed by the Clean Water Rule. The agencies made clear in the Preamble to the final Clean Water Rule and in information published on their websites that there will also be no change to implementation of the section 404(f) exemptions resulting from the Clean Water Rule. The public can be certain that the section 404(f) exemptions will continue to be applied as they have been since their enactment in 1978.

**Conaway 11.** On December 14, 2015, the Government Accountability Office (GAO) published a legal opinion finding that the EPA violated federal law by engaging in *covert propaganda* and *grassroots lobbying*. How do you plan to rectify what many in the agricultural community consider a flawed rule from a flawed process?

**EPA Response:** In promulgating the Clean Water Rule, the EPA complied fully with the CWA and all laws applicable to the rulemaking process. The GAO opinion did not comment on or examine the EPA's rulemaking process. The GAO evaluated the EPA's use of certain social media platforms tools during the time of the rulemaking to determine whether they violated restrictions that prohibit using federal funds for either (1) indirectly lobbying Congress in support of, or in opposition to pending legislation or (2) publicity that is self-aggrandizing, purely partisan, or conceals the agency's role in sponsoring the material. After examining a database of social media outreach materials, the GAO took issue with only a single EPA blog post with two hyperlinks to articles on third party websites and the EPA's use of a social media tool called "Thunderclap." The alleged violations had no impact on the EPA's rulemaking process or on the EPA's compliance with any law applicable to the rulemaking, including the Administrative Procedure Act.

**Conaway 12.** What role did USDA play in the development of the WOTUS rule? When did EPA begin the process of developing the rule? When did you first engage USDA?

**EPA Response:** The agencies consulted with other federal agencies, including the U.S. Department of Agriculture, throughout the process of developing the Clean Water Rule. USDA provided comments on the Clean Water Rule to the Office of Management and Budget (OMB) consistent with the interagency review process governed by Executive Order 12866. EPA and the U.S. Army Corps of Engineers used these comments in working to meet a key Clean Water Rule goal of improving clarity and predictability for farmers and reducing regulatory burdens on agricultural lands. The agencies began consulting with the USDA staff as a part of the process to prepare jurisdictional guidance during the first term of the Obama administration and throughout the subsequent process of developing the Clean Water Rule. USDA has consistently emphasized agriculture's outstanding stewardship track record in delivering water resource benefits locally, regionally, and nationally.

**Conaway 13.** Some observers suggest that the proposed 70 parts per million (ppm) standard for ozone is below naturally occurring background levels. By reducing the ozone standard to 70 ppm, large swaths (largely rural) of the country will likely be designated as nonattainment. If this is correct, the new standard would be virtually unachievable. In light of this, how does EPA justify the billions, if not trillions, of dollars of burdensome costs that could be expected to be borne ultimately by the American people and their communities to attempt to comply with an impossible standard?

**EPA Response:** The EPA projections show that the vast majority of U.S. counties will meet the revised standards by 2025 without taking additional action to reduce emissions. Existing and proposed federal rules, such as Tier 3 vehicle standards, Mercury and Air Toxics Standards, and measures to address the 2010 sulfur dioxide National Ambient Air Quality Standards (NAAQS) will help states meet the standards by reducing ozone forming pollution.

Uncontrollable background concentrations of ozone, from sources like natural events, e.g., wildfires, or foreign emissions, are not expected to preclude attainment of a revised ozone standard with a level of 70 ppb. In addition, Congress established requirements for implementing the health based NAAQS standards that recognize issues like background ozone and interstate transport to ensure that states are not responsible for emissions they cannot reasonably control. The Clean Air Act does not require states to demonstrate attainment of NAAQS in all areas. Areas that are significantly affected by emissions outside their control may receive special consideration.

When setting the level of a NAAQS, the EPA is prohibited by law from considering the costs of implementation. Courts, including the Supreme Court, have held uniformly that the EPA may not consider issues of implementation costs when establishing NAAQS. The Clean Air Act directs the EPA to set NAAQS at a level requisite to protect public health with an adequate margin of safety and to protect the public welfare from any known or anticipated adverse effects of air pollutants.

**Conaway 14.** Our country has made great strides in reducing our ozone levels—roughly 33% reduction since 1980—by keeping the standards practical and attainable. However, EPA is now pursuing a standard that cannot be achieved and therefore whose health benefits would never be realized. What is EPA’s justification for creating an ozone standard that is set so low that it cannot be reasonably achieved while recognizing that the health benefits from such a standard will never be reached?

**EPA Response:** The EPA believes that a primary ozone standard with a level of 70 ppb will substantially improve public health protection across the country and will provide the adequate margin of safety the law requires – including for children, who are one of the groups most at risk from ozone exposure. The public health benefits of a 70 ppb ozone NAAQS are significant – estimated at \$2.9 to \$5.9 billion annually in 2025. It is also worthwhile to note that the EPA projections show that the vast majority of U.S. counties will meet the revised standards by 2025 without taking additional action to reduce emissions. Existing and proposed federal rules, such as Tier 3 vehicle standards, Mercury and Air Toxics Standards, and measures to address the 2010 sulfur dioxide NAAQS will help states meet the standards by reducing ozone forming pollution.

**Conaway 15.** What specific impact would being designated as a nonattainment area under the new standard have on job creation and economic growth in rural communities?

**EPA Response:** Once the EPA sets a new air quality standard, or revises an existing standard, the Clean Air Act requires the EPA to designate areas as meeting the standards (attainment areas) or not meeting them (nonattainment areas) based on local air quality. The agency also may designate an area as unclassifiable, meaning there is not enough information to make a determination. States make area designations recommendations, and the EPA works closely with states and tribes as it finalizes the initial designations and boundaries for any nonattainment areas.

All states with nonattainment areas must develop emission inventories and implement a preconstruction permitting program designed to provide additional air quality safeguards for those areas. For nonattainment areas classified “moderate” or higher, which are unlikely to be rural areas, states must develop state implementation plans showing how the areas will meet the standards. These plans must include reasonable available control technology standards for certain types of ozone producing emission sources in the nonattainment area. They also can include federal measures that will result in local emissions reductions, such as national mobile source requirements. States may take area-specific considerations into account in developing these plans.

**Conaway 16.** EPA finalized the recent 2015 stringent ozone standard when it hadn’t even released implementation rules for the last standard set in 2008. In fact, states were forced to make designations under the standard without final implementation rules from EPA. Doesn’t it make sense to get the 2008 standard implemented before burdening states with double-regulation?

**EPA Response:** The EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act, underpinned by a wealth of previously issued EPA rules and guidance. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the 2015 ozone NAAQS. Planning and implementation work to meet the 2015 ozone standard will build on progress states have already made to plan for and meet the 2008 standards. In particular for areas where states are still actively working toward attaining the 2008 ozone NAAQS, the EPA is committed to helping air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act’s requirements for the 2015 standards.

**Conaway 17.** The National Association of Clean Air Agencies testified to EPA that the new ozone standard “will have a profound impact on the work of state and local air pollution control agencies.” Did EPA assess what impact implementing the new ozone standards would have on state and local agencies already implementing the 2008 standard – shouldn’t these standards be harmonized?

**EPA Response:** As provided in the previous answer, the EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act, underpinned by a wealth of previously issued EPA rules and guidance. Planning and implementation work to meet the 2015 ozone standard will build on progress states have already made to plan for and meet the 2008 standards. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the revised ozone NAAQS. In particular for areas where states are still actively working toward attaining the 2008 ozone NAAQS, the EPA is

committed to continue helping air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act's requirements for the 2015 standards.

**Conaway 18.** EPA chose to project the costs of its new ozone standard to 2025, eight years after counties will be designated as nonattainment. What consequences will those counties face while designated nonattainment?

**EPA Response:** The Clean Air Act requires that within three years of the EPA setting a new air quality standard, or revising an existing standard, the EPA must designate areas as meeting the standards (attainment areas) or not meeting them (nonattainment areas) based on local air quality. The agency also may designate an area as unclassifiable, meaning there is not enough information to make a determination. Governors make initial designations recommendations, and the EPA works closely with states and tribes as it determines initial designations and boundaries for nonattainment areas.

All states with nonattainment areas must develop emission inventories and implement a preconstruction permitting program designed to provide additional air quality safeguards for those areas. States with nonattainment areas classified as "Moderate" or higher must develop state implementation plans showing how the areas will meet the standards. These states also must adopt reasonable available control technology standards for certain types of emission sources in the nonattainment. They also can include federal measures that will result in local emissions reductions, such as national mobile source requirements.

**Conaway 19.** EPA chose to project the costs of its new ozone standard to 2025. Since EPA bases its entire economic analysis on predicted 2025 air quality, will the Agency support extending compliance deadlines under the standards to 2025?

**EPA Response:** The Clean Air Act governs the process and timing for initial area designations and associated compliance deadlines after the EPA establishes a new or revised NAAQS. Following Clean Air Act requirements, the EPA anticipates the following schedule for the 2015 ozone NAAQS:

- By October 2017: the EPA issues final area designations; those designations likely would be based on 2014-2016 air quality data. If preconstruction permitting program requirements for the nonattainment area do not already exist, federal permitting regulations apply until they are replaced by state adopted programs;
- 2019: States submit area-specific inventories of ozone producing emissions;
- 2020 to 2021: For nonattainment areas classified as "Moderate" and above, states, and any tribes that choose to do so, complete development of implementation plans, outlining how they will reduce pollution to meet the standards. State and tribal plans can include

federal measures, and any local or statewide measures needed to demonstrate that a nonattainment area will meet the standards by its attainment date; and

- 2020 to 2037: Nonattainment areas are required to meet the primary (health) standard at varying deadlines throughout this time, depending on the severity of an area's ozone problem.

**Conaway 20.** I am concerned that EPA continues to propose new programs like the Urban Waters program and the Resilient Finance Center rather than finding ways to support these goals through the Agency's core programs. What is EPA doing to ensure that these programs aren't creating a fragmented approach to water resource protection?

**EPA Response:** The Urban Waters Program and the Water Infrastructure and Resiliency Finance Center are examples of initiatives that cross water program boundaries and are most effectively supported in ways that reflect this multiprogram relationship. The Water Infrastructure and Resiliency Finance Center, for example, identifies financing approaches to help communities make better informed decisions for local needs such as drinking water, wastewater, and stormwater infrastructure. The Center increases collaboration between state and local governments and the private sector, expands public-private partnerships, and increases the use of federal credit programs. These are all actions that reach beyond the activities of one core federal water program and, instead, serve to enhance and strengthen multiple federal, state, and local objectives. We believe that managing these programs outside a single core program, therefore, allows the EPA to more effectively integrate and support multiple water efforts and to take advantage of these initiatives and reduce potential fragmentation in federal, state, and local clean water programs.

**Conaway 21.** Will EPA use the time the Supreme Court has provided everyone to better understand electric grid operations so you will better understand and account for the cost and reliability issues associated with your assumptions about unprecedented growth in renewables? Do you agree with President Obama and Secretary Vilsack that agricultural products can help reduce the Nation's carbon emissions? Why does the Clean Power Plan by default treat carbon from agricultural crops the same as fossil fuel emissions?

**EPA Response:** On February 9, the Supreme Court granted a motion to stay the Clean Power Plan. As a result of that action, states are not currently required to submit a state plan or a request for extension by September 6, 2016.

A core principle of the Clean Power Plan (CPP) is the importance of providing states the flexibility to develop their own approaches to address carbon dioxide (CO<sub>2</sub>) emissions. This flexibility recognizes the unique circumstances of each state when it comes to their energy mix, and their approaches to energy efficiency and renewable energy. In the CPP, states have the flexibility to choose whether or not to include biomass as part of their state plans, and if so, the flexibility to describe the types of biomass that are being proposed for use under their state plans, how those proposed feedstocks or feedstock categories should be considered as "qualified biomass" (i.e., a biomass feedstock that is

demonstrated as a method to control increases of CO<sub>2</sub> levels in the atmosphere), and explain the proposed valuation of biogenic CO<sub>2</sub> emissions.

The EPA generally acknowledges the CO<sub>2</sub> and climate policy benefits of waste-derived biogenic feedstocks and certain forest- and agriculture-derived industrial byproduct feedstocks. The final rule also provides that states may demonstrate that the use of agricultural and forest biomass feedstocks appropriately control increases of CO<sub>2</sub> levels in the atmosphere.

**Conaway 22.** How long has EPA been working on its Biogenic Accounting Framework for agricultural crops? When does EPA anticipate finishing that process?

**EPA Response:** As part of the EPA's effort to advance the technical understanding of the role of biomass in addressing greenhouse gas emissions, in November 2014 the EPA released the second draft of its scientific report, Framework for Assessing Biogenic Carbon Dioxide for Stationary Sources. The revised report takes into account Science Advisory Board peer review recommendations on the 2011 Draft Framework, as well as the latest information from the scientific community and other stakeholders. In February 2016, the biomass SAB Advisory panel delivered its draft final peer review report to the full chartered SAB for a quality review. The full chartered SAB held a public, in person quality review meeting at the end of March 2016 and offered its recommendations on the draft final peer review report to the biomass SAB Advisory Panel. EPA is reviewing recommendations from the full chartered SAB as well as those finalized by the biomass SAB Advisory Panel. More information on the chartered SAB meeting can be found at <http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD>.

**Conaway 23.** The public is threatened by insect borne diseases - West Nile Virus is a good example. Some of the critical products used to control mosquitoes are also the backbone of Integrated Pest Management plans. These include a class of pesticides known as OP's. Tell me more about EPA's plans for OP's used to protect public health against very dangerous and prolific pests. How is EPA considering the importance of these products to human health in its risk assessments? Is EPA following established protocols for consultations with CDC and other federal agencies with public health expertise?

**EPA Response:** The EPA recognizes that certain organophosphate pesticides are important tools in strategies to control pests that vector diseases. The EPA considers the benefits, both public health and others, of these pesticides, along with their risks, before making any regulatory decisions. The EPA consults with the Centers for Disease Control and Prevention when making a regulatory decision for any pesticide used to control a pest of public health significance. In addition, EPA consults with the Secretary of Health and Human Services on the identification of pests of significant public health importance and solicits the views of the Secretary on certain environmental pesticide regulations. The EPA also frequently consults with other interested stakeholders to ensure that the agency has a complete picture of the benefits and have properly evaluated any proposed

mitigation. Fortunately there are a number of other EPA registered products that can be used for effective mosquito control.

The EPA is currently evaluating the organophosphates in our statutorily mandated registration review program. The agency will take comment on our assessments before consideration of any risk management. In addition, the EPA will engage with the registrants and the public health community to ensure that we are considering all relevant data in our assessments. Where states, localities, other federal agencies, and user groups have relevant information that could aid in the analysis, the agency will utilize this information as well. Similarly, as new scientific information becomes available that changes our understanding of potential risks as well as pesticide efficacy, we can revisit our decisions.

**Conaway 24.** Exactly how many new products or product uses have been brought into the market, and, how many products and uses have been restricted or effectively lost under your tenure as Administrator?

**EPA Response:** Approximately 170 new active ingredients and more than 1700 new uses of previously registered active ingredients have been registered during my tenure. During the same time period, the EPA made about 165 registration review decisions on active ingredients and approximately 300 uses have been cancelled. Registration review is the agency's current re-evaluation program, which focuses on the pesticide active ingredient rather than products or uses.

Of the 165 registration review decisions on active ingredients, about half of these decisions required no changes or minor label changes. Labeling changes can include removing uses, reducing application rates and adding protections for vulnerable populations to address specific human health and ecological concerns. They also improve clarity so that the user can better understand the label and use the product safely. The other half of the decisions made involved voluntary cancellation by the registrants primarily for business reasons.

**Conaway 25.** Rather than going through normal public process to propose to cancel a registration - has the Agency ever asked a court to order to vacate a registration? If so, please describe those circumstances.

**EPA Response:** Subsequent to registering Enlist Duo, the EPA became aware of previously existing information about possible synergistic effects that had not been considered as part of the initial registration decision. As a result, the agency could no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. The EPA therefore sought from the Court an order of remand with vacatur. This is the first time that the EPA has asked a court to vacate a pesticide registration.

**Conaway 26.** EPA is supposed to take into account the benefits of a product, such as protection of the public health from disease-carrying pests, protection of our nation's buildings and infrastructure, protection of the food supply. However, recent EPA activities appear to focus disproportionately on the hazard side of that assessment while discounting factors like exposure and benefits. What additional data does the EPA need in order to better account for pesticide benefits?

**EPA Response:** Under FIFRA, the EPA must ensure that a pesticide does not cause "unreasonable adverse effects." An important factor in that determination is the consideration of other factors including the benefits associated with the use of the pesticide. The EPA typically starts the evaluation of a pesticide by conducting risk assessments to determine if there are any "risks of concern" before weighing the other factors. However, before taking any registration action, the EPA considers the benefits the pesticide offers and the impacts of any mitigation option on the users of the pesticide (that is, any loss of benefits). A risk-benefit analysis is applied to ecological and occupational risks under FIFRA.

When considering the use of a pesticide on food, the agency must consider all dietary risk from residues that result from a pesticide use and establish a tolerance (or exemption) under the Federal Food, Drug, and Cosmetic Act (FFDCA). Generally, the safety standard for the review of pesticide chemical residues under the FFDCA is a risk-based standard that requires the EPA to make a "reasonable certainty of no harm" determination when it establishes a pesticide tolerance to regulate the amount of pesticide residue in food. When making a determination under FFDCA, the EPA normally considers options for meeting the safety standard and tries to select the one with the least impact on the user community. If the safety standard of FFDCA is not met, benefits cannot be considered in order to allow the use of the pesticide.

Benefits may be considered when making a regulatory decision under FIFRA when considering ecological or risks posed to workers. In assessing the benefits of the use of agricultural pesticides, the EPA largely relies on information generated by the land grant university system, USDA, and other stakeholders. Information on non-agricultural uses, including public health, residential, and industrial uses, is more limited and the EPA relies heavily on our public process to solicit information about the pests targeted by specific pesticides and the advantages a specific pesticide may have in particular situations.

**Conaway 27.** I understand that EPA will complete and release its 5-year reissuance of the Clean Water Act-based Pesticide General Permit. What changes should we expect to see in the reissued Pesticides General Permit based on the new Clean Water Rule expansion?

**EPA Response:** The Clean Water Rule does not itself establish any new requirements regarding the use of pesticides. As a result, issuance of the Clean Water Rule does not change the National Pollutant Discharge Elimination System (NPDES) requirements regarding application of pesticides to waterbodies. The EPA's experience with the

Pesticide General Permit (PGP) during the last four years demonstrates it is working well to ensure that use of pesticides is being managed to minimize potential regulatory burdens while effectively protecting the nation's water resources and public health. Conditions and requirements in the EPA's proposed PGP remain largely unchanged from the 2011 PGP. Final decisions regarding reissuance of the PGP will reflect public input and coordination with stakeholders.

**Conaway 28.** Please provide a comprehensive list of *all* agency actions, not just rulemakings, over the last 8 years and those planned through the end of 2016 that restricted or have the potential to restrict existing or new uses of pesticides.

**EPA Response:** The pesticide registration review process began in 2006 with the first decisions being made a few years later. To date, 165 decisions have been made. Of these decisions, 83 involved requests from the registrants to voluntarily cancel their registrations, in most cases for business decisions that were independent of the agency's review. For the remaining 82, many required no change to the registration or minor label clarification to make it easier for the user to understand and use the product correctly. The EPA's anticipated registration review schedule can be found at [www.epa.gov/pesticide-reevaluation/registration-review-schedules](http://www.epa.gov/pesticide-reevaluation/registration-review-schedules).

During the same time period, the EPA has registered approximately 170 new pesticide active ingredients and over 1,700 new uses of already-registered active ingredients, providing numerous new products for use in agricultural and non-agricultural settings. These newly registered products are designed to address emerging pest pressures and will have a significant role in the marketplace.

Of these regulatory decisions to restrict or cancel certain registrations, the EPA made these decisions after careful consideration of all available data and consistent with existing statutory requirements. For example:

- In 2010, the EPA announced its decision to terminate all uses of endosulfan due to unacceptable risks to farmworkers and wildlife. The EPA signed a Memorandum of Agreement with the registrants of endosulfan that resulted in voluntary cancellation and provided for a phase-out of all existing endosulfan uses in the United States in order to allow time for growers to transition to newer alternatives;
- In 2012, the EPA limited the use of chlorpyrifos by significantly lowering pesticide application rates and creating "no-spray" buffer zones around public spaces, including recreational areas and homes, due to concerns for unacceptable risks to children and bystanders;
- In 2014, the EPA cancelled propoxur pet collars. In the fall of 2013, the EPA completed the propoxur pet collar risk assessment. The EPA's risk assessment indicated risks of concern to children from exposure to pet collars containing propoxur;

- In 2015, the EPA reached an agreement with Reckitt Benckiser, the manufacturer, to cancel all distribution of 12 consumer use d-CON products that did not meet the EPA's current safety standards, raising concerns for risks to children and pets. Additionally, eight of the 12 products pose unacceptable risks to certain wildlife;
- In 2015, the EPA proposed to revoke all chlorpyrifos tolerances due to concerns with estimated exposure from drinking water in certain watersheds. A final tolerance rule is anticipated in March 2017;
- On November 24, 2015, while the issuance of the initial registration was being challenged in federal court, the EPA sought the remand and vacatur of the Enlist Duo registration because the EPA became aware of previously existing information about possible synergistic effects that had not been provided to the EPA or considered as part of the initial registration decision. The EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA;
- On July 2, 2013, the Pollinator Stewardship Council and others, petitioned for review of the sulfoxaflor registration in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion, finding that the registration was not supported by substantial evidence to demonstrate no unreasonable adverse effects to honey bees would result from the registration of sulfoxaflor. Although the initial sulfoxaflor submission contained all the data the EPA determined was necessary by the EPA for registration of a new agricultural insecticide, the Court vacated the registrations and remanded them to the EPA to "obtain further studies and data regarding the effects of sulfoxaflor on bees as required by the EPA regulations." The vacatur of the sulfoxaflor registrations became effective November 12, 2015. As the registrations were no longer in effect under FIFRA, on the same date the EPA issued a cancellation order to address existing stocks. Although the product registrations were vacated, the tolerances for sulfoxaflor residues on treated commodities that were established under the FFDCA, remain in place; and
- On March 4, 2016, the EPA issued a notice of intent to cancel the registration of four pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. The particular condition obligated the registrants to request cancellation if, after receiving additional required data, the EPA determined that use of flubendiamide did not meet the FIFRA standard for registration. Prior to issuing the notice, the EPA concluded that the continued use of flubendiamide will result in unreasonable adverse effects on the environment, particularly benthic invertebrates, which are an important part of the aquatic food chain, particularly for fish.

Over the past 8 years, the EPA has issued a number of regulations with the intention of providing clarity to the regulated community and other stakeholders or to update information that has become inaccurate or out of date. Examples of these rulemaking efforts include:

- Minimum Risk (Published 12/28/2015): This final rule more clearly describes the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. These changes maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and the EPA as to whether a product is in compliance with the exemption;
- Crop Grouping (Published Phase 1: 12/7/2007; Phase 2: 12/8/2010; Phase 3 8/22/2012; Phase 4: anticipated 2016): These final rules are likely to reduce the number of residue chemistry studies required to establish a tolerance for a crop within these crop groupings because instead of testing each crop individually, only the representative crops would need to be tested. Thus, the new crop groups ease the process for an entity to request and for the EPA to set pesticide tolerances on greater numbers of crops. Pesticides will be more widely available to growers for use on crops, particularly specialty crops;
- Data Requirements for Antimicrobials (158W) (Published 5/8/2013): the EPA revised the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practice, and to provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The EPA would use this information to conduct risk assessments for a particular pesticide;
- Prions as Pests (Published 2/28/2013): In 2003, the EPA determined that a prion (proteinaceous infectious particles) is a "pest" under FIFRA and that a product intended to reduce the infectivity of prions on inanimate surfaces (i.e., "prion product") is considered to be a pesticide. The EPA believes that regulating prion-related products protects human health and the environment against unreasonable adverse effects and ensures that such products are effective;
- Export Labeling (Published 1/18/2013; Revisions Published 12/19/2014): the EPA revised the regulations pertaining to the labeling of pesticide products and devices that are intended solely for export. Pesticide products and devices intended solely for export are now able to meet the agency's export labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States. Collateral labeling ensures the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in, and consistent with the applicable requirements of the importing country; and
- Data Compensation (Published 2/5/2014): the EPA revised its regulations governing procedures for the satisfaction of data requirements under FIFRA, which are codified in 40 CFR Part 152, subpart E. These provisions include, among other things, procedures for the protection of exclusive use and data compensation rights of data submitters. The EPA updated the regulations to accommodate statutory changes and changes in practice

that have occurred since 1984; to make minor changes to clarify the regulations; and to make changes that would simplify the procedures and reduce burdens for certain data submitters. The revisions did not otherwise make substantive changes to the requirements.

At times, however, the EPA has determined that significant changes to its regulations are needed to improve public health. For example, in November 2015, the EPA finalized revisions to the Agricultural Worker Protection Standard. This final rule revised the federal regulations issued under FIFRA that direct agricultural worker protection (40 CFR Part 170). The changes reflected current research on how to mitigate occupational pesticide exposure to agricultural workers and pesticide handlers, and strengthened the protections provided to agricultural workers and handlers under the worker protection standard. The changes improved elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies, thus preventing exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. The EPA is working closely with affected stakeholders, including state agricultural agencies, to ensure that they have the necessary information and training to implement these new protections.

Similarly, the EPA is now working to develop a final rule to revise the federal regulations governing the certified pesticide applicator program (40 CFR Part 171). This action is intended to improve the competence of certified applicators of restricted use pesticides (RUPs) and to increase protection for noncertified applicators of RUPs operating under the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators. State agricultural agencies, as well as many other stakeholders, provided valuable comments and suggestions in response to the EPA's proposed rule. We will work with stakeholders to ensure that the revised competency standards can be implemented effectively by state agencies.

**Conaway 29.** Federal law includes very specific actions that a federal agency must take before promulgating new regulations. The Office of Pesticide Programs has circumvented this process by sending pesticide registrants letters that outline new regulatory provisions. This "regulation by letter" procedure was used by EPA in 2013 to mandate registrants include pollinator statements and a graphic on certain products, and in 2009 for a labeling initiative. What is EPA's rationale for circumventing the Administrative Procedure Act (APA), which includes notice and comment, economic and small business impact analysis, etc.?

**EPA Response:** The EPA does not "regulate by letter" and FIFRA does not provide for such a regulatory mechanism to make changes to pesticide registrations. The EPA pesticide program is a licensing program that is based on an adjudicatory system. As a licensing program, the agency must ensure that the license complies with the law and continues to comply with the law. As such, decisions to grant a new license or change /modify an existing license are not subject to APA rulemaking, but the procedural

requirements of FIFRA. When the EPA receives new information and determines that the license may lead to unreasonable adverse effects on the environment, the agency may offer the registrant a way to correct the imbalance in a timely manner. The August 2013 letter regarding labeling changes for the neonicotinoid insecticides is one example. However, if the registrant chooses not to address the concerns raised in such an offer, the agency can take appropriate steps under FIFRA to compel any necessary changes to the pesticide registration to mitigate unreasonable adverse effects on the environment. The letter itself is not self implementing; in the absence of voluntary agreement from a registrant, FIFRA prescribes steps that the agency must take to impose new mitigation measures.

**Conaway 30.** EPA's honeybee acute toxicity proposal would restrict approved crop protection tools from use when a grower is under a pollination contract. The proposal clearly did not have the support of conventional or organic growers, or the national beekeeper organizations, or the USDA, which sent a letter to the Agency criticizing the proposal. Honeybees are not native species; they are essentially livestock and the property of the beekeeper. Why is EPA attempting to regulate contracts between private parties? Has the Agency produced an analysis to show the benefit expected if the rule is implemented?

**EPA Response:** With greater attention put on protecting pollinators as well as their important role in agricultural production, the EPA's acute mitigation strategy, *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products*, is aimed at providing greater protection to bees where acute risk is presumed to be the highest, namely when nearly certain exposure (i.e., contract pollination scenarios) and presence of an acutely toxic pesticide coincide. The intent of the proposed acute mitigation strategy is to protect managed (contracted) bees at commercial pollination sites, and also likely provide protection for other pollinators near the treatment area.

The proposed approach is to clarify and strengthen the existing language for the acutely toxic compounds in the immediate term. The agency will also assess each compound under the registration review program, with a robust data set identified in our *Risk Assessment Framework for Pollinators* that also evaluates potential sublethal and chronic impacts to pollinators at both the individual and colony level. As a result, chemical-specific, risk based labeling will be developed. As part of its planning and analysis prior to issuing its proposal, the agency did consider the potential cost to growers.

The EPA is currently reviewing the wide range of comments it received in response to the proposal. Based upon comments received, we are developing options on moving forward. While doing so, the agency will continue to weigh both the level of protection to bees, and the potential impact to growers.

**Conaway 31.** Environmental activists recently sued the EPA claiming that the agency should regulate seeds treated with systemic pesticides as pesticides themselves and regulate those seeds under FIFRA. Congress has expressed its intent that seeds are not subject to the same regulatory requirements as applied pesticides, and in recent years has

found that treated seeds are safe and offer significant value to farmers, which is consistent with EPA's long-held view. Furthermore, restricting seed treatments would likely lead to them being replaced with spray or soil applications and that switch would not result in improved environmental protection. Do you intend to vigorously defend the agency's determination that economically-beneficial coated seeds are "treated articles?"

**EPA Response:** With respect to the litigation filed by public interest groups, on March 14, 2016, the EPA filed a motion with the district court in the Northern District of California to dismiss the case against the EPA. A hearing on this motion was held on May 12, 2016, and the following day the court issued an order deferring a decision on the merits of the EPA's motion to dismiss until the EPA produced an administrative record. The EPA has complied with the court's order and expects the court to address its jurisdiction (the subject of the motion to dismiss) during summary judgment proceedings. Under the current litigation schedule, summary judgment motions are to be filed in September and should be argued in October 2016.

**Conaway 32.** Seed treatments deliver a very precise application that shields seeds from the insects and diseases that exist in the soil during early developmental stages. Do you agree that seed treatments reduce the environmental impact of the production process by decreasing the number of spray applications of agrichemical products lessening exposure to non-target species, including humans, pollinators and the environment?

**EPA Response:** In general, the EPA agrees that seed treatments are effective at reducing environmental exposure and impact, as compared to spray applications of agrichemical foliar products, to humans and the environment. In addition, the EPA has engaged in discussions with the American Seed Trade Association, equipment manufacturers, and pesticide registrants to encourage broader adoption of best management practices intended to reduce the potential for drift of contaminated dust during the planting of pesticide-coated seeds that have resulted in incidents to honeybees. These efforts have included the development of alternative lubricants used in pneumatic planters to reduce dust generated through the abrasion of treated seed during planting as well as the development of more effective seed coatings to enhance pesticide adherence to the seed.

**Conaway 33.** When this Committee passed both HR. 872 in the 113<sup>th</sup> Congress and HR. 897 last year we discussed the outbreaks of West Nile Virus and even concerns about Malaria across many regions of the country. Today, there is a new threat to human health called the Zika virus, which is also transmitted through mosquitos. The World Health Organization has gone so far as to declare a public health emergency of international concern. There are no vaccines or a reliable diagnostic test. I believe that America will be better adept to combat the spread of the virus with our world renowned researchers and response by the public health community. However, our country is currently being hamstrung by an ill-advised court decision that was in contradiction with EPA's own assessment under the Clean Water Act and the Federal Insecticide, Fungicide, and Rodenticide Act. In some states, the burden and liabilities of obtaining a duplicative NPDES permit are limiting or delaying mosquito control applications that protect human health. Will the Administration support the passage of this important legislation?

**EPA Response:** The Administration believes that legislation removing CWA Act protections for public health and water quality is not the answer for effective and timely action to respond to the threat of mosquito-borne illness.

**Conaway 34.** Major farm organizations have written EPA concerning the need for new, effective weed management tools. Prominent academics, farm group leaders and many others have said multiple modes of action are the most effective way to deal with weed resistance issues while preserving environmentally beneficial cropping systems like no-till or conservation tillage. Yet when it comes to crop protection product registrations at EPA, some innovative products that can help growers meet these goals have been either sitting at your agency for several years, or in some cases courts have intervened to vacate registrations. What conversations are you having with USDA and the industry to minimize the concerns raised in court actions and to ensure the near-term availability of new, more effective weed management chemistries?

**EPA Response:** The EPA recognizes the negative impacts of weed resistance and understands the needs of growers for new weed control technology. The EPA's review of herbicides proposed for use on genetically modified seed requires thorough and scientifically rigorous assessments for both human health and the environment. The agency has intensified communications and information sharing with USDA in handling these actions, and is building a framework for a streamlined process that also addresses new measures for avoiding the onset of new resistance issues.

Because the emergence of herbicide resistance is an increasing problem in the United States, the EPA has been working directly with the USDA and industry to construct a comprehensive resistance management program. By developing these new strategies, the EPA hopes to promote a more efficient registration process while simultaneously preserving the longevity of important new herbicide tools. Meanwhile, the agency will continue to work closely with the USDA in the review of herbicides submitted in association with herbicide-tolerant traits to ensure that our two agencies perform a thorough scientific review of the potential impacts on human health and the environment associated with the proposed use of additional herbicides on herbicide-tolerant crops.

In addition, in the spring of 2016, the EPA requested public comment on two Pesticide Registration Notices (PRNs) that focus on strategies to combat or slow pesticide resistance, and preserve the useful life of pesticide chemistries. One of these PRNs aims to improve resistance management information contained on the labels of all conventional pesticide products.<sup>1</sup> The other PRN focuses on the agency's proposed strategy for addressing herbicide resistance.<sup>2</sup> The EPA expects to finalize these two PRNs in late 2016.

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<sup>1</sup> <https://www.epa.gov/pesticide-registration/prn-2016-x-draft-guidance-pesticide-registrants-pesticide-resistance>

<sup>2</sup> <https://www.epa.gov/pesticide-registration/prn-2016-xx-draft-guidance-herbicide-resistance-management-labeling-education>

**Conaway 35.** EPA recently asked the 9<sup>th</sup> Circuit Court of Appeals to remand a pesticide registration back to EPA for further review because of concerns under the Endangered Species Act. This is the only time ever where EPA has attempted to vacate a pesticide registration through a court action. Currently under FIFRA, EPA is required to comply with a number of procedural safeguards before a pesticide registration can be cancelled, which they have failed to do. What was the Agency rationale for taking such an unusual step of asking a Court to require EPA to review the registration of a product so recently approved for use and why is the Agency now trying to use the Courts as a means to regulate?

**EPA Response:** The EPA felt compelled to seek remand and vacatur because the EPA discovered, after granting the registration for Enlist Duo, that Dow had made claims of “synergistic herbicidal weed control” in its Provisional and Non-provisional patent applications to the U.S. Patent and Trademark Office for Enlist Duo. This new information suggests the two active ingredients used in combination could result in greater toxicity to non-target plants than believed by the EPA at the time the agency granted the registration. This information was not provided to the EPA by Dow prior to the EPA issuing the Enlist Duo registration. This new information could lead the EPA to a different decision on the restrictions on use of Enlist Duo, including those necessary to ensure the protection of listed species in the context of the Endangered Species Act.

Because the EPA had become aware of previously existing information about possible synergistic effects that it did not consider, the agency could no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in FIFRA and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. The EPA therefore sought from the Court an order of remand with vacatur.

**Conaway 36.** The United States has the world’s most rigorous pesticide registration and review processes. We regulate pesticide by assessing ‘risk’ to determine whether and how a product can be used safely. In evaluating risk, ‘hazard’ (whether something can cause harm) and ‘exposure’ (whether something you’ll be exposed to harm) are balanced against the benefits of using a product. This is something EPA should be confident in and proud to defend. As a matter of fact, EPA does a great job defending the merits of our risk-based system when commenting on the EU’s precaution-based regulatory scheme. But, recently it seems when EPA regulatory decisions are challenged in the US, you seem reluctant to defend or, even more troubling, unable to properly provide evidence of the Agency’s scientific decisions. How can you better inform the public and skeptics that the products EPA registers are thoroughly tested and protective of human health, vulnerable species and the environment?

**EPA Response:** The EPA agrees that it has one of the world’s most rigorous registration and reevaluation processes. The agency always strives to base its decisions on the best available science. However, science is constantly evolving, and new scientific information can come to light at any time and change our understanding of potential risks from pesticides. If any pesticide is found to present risks to human health or the

environment that cannot be mitigated or managed through other measures, the agency has to make a finding that the pesticide no longer meets the FIFRA standard for registration or under the Federal Food, Drug, and Cosmetic Act for pesticide tolerances. In that case, then the agency will move quickly to take appropriate regulatory action. Any such action, however, would have to be supported by the best available, peer-reviewed science. The EPA scientific assessment approaches are publically available at <http://www2.epa.gov/pesticide-registration/understanding-science-behind-epas-pesticide-decisions>.

**Conaway 37.** There have been several instances where courts, local governments or other organizations have challenged EPA regulatory decisions. What can Congress do to educate the public, localities, courts and other institutions about the rigors of the pesticide registration process and to increase the public's confidence in EPA's pesticide registration decisions?

**EPA Response:** As stated in the response above, the EPA agrees that it has one of the world's most rigorous registration and reevaluation processes. The agency always strives to base its decisions on the best available science. In addition, the EPA believes that by making its decisions in a transparent manner, including through the active solicitation of public participation in the process, we demonstrate the scientific soundness of our decisions.

**Conaway 38a.** The Committee has heard about a serious matter regarding EPA policies based on human research data that may not be reliable. For years, EPA relied on hundreds of quality studies evaluating all aspects human susceptibility to pesticides called organophosphates – otherwise known as OP's. These included studies designed to make sure that children would be protected. Even though EPA used those high-quality assessments for 20 years; EPA now relies primarily on three epidemiology publications and some journal articles in which EPA, I am told, EPA does not have access the raw data to determine if these studies are reliable or accurate. The Committee has been advised that Columbia University - who conducted the key study - refused to provide the raw data to EPA even though EPA provided funding for the study. So, it appears EPA is relying on information based on raw data that cannot be reviewed for accuracy. If it is correct that EPA has not gotten access to that raw data, federal regulations designed to enhance the credibility of the federal rulemaking process have likely been violated. Data Quality Act violations and conflict of interest violations could have also occurred.

EPA held a meeting in May 2013 with researchers from Columbia University about the Columbia Study. Is there a transcript of the discussion that took place at that meeting? Were minutes taken at the meeting and made available?

**EPA Response:** The agency wrote a summary of the 2013 meeting with researchers from Columbia University. This summary is contained in “Appendix 6 Columbia Center for Children’s Environmental Health (CCCEH) Epidemiology Data Acquisition “Raw Data Request” of EPA’s December, 2014 human health risk assessment for chlorpyrifos which can be found at [www.regulations.gov](http://www.regulations.gov) in docket ID number: EPA-HQ-OPP-2008-0850-0195, (Drew et al, D424485, December 29, 2014).

**Conaway 38b.** Did the federal government provide any funding for any or all of the three epidemiology studies, most notably the study from Columbia University’s Center for Children’s Health commonly referred to as the Columbia Study, the “CHAMCOS” study and, also, the Mt Sinai study which were relied upon by the Agency to raise issue about potential effects on infants and children in the human health assessment and Proposed Rule to revoke tolerances for chlorpyrifos? Please provide details on any and all funding EPA provided for any portion of the three studies.

If yes:

Does the Agency have in its possession all the raw data from the studies? (Raw data would include but is not limited to interview data with participants, blood and urine analysis, interviews with the children, etc)

For which of these studies does EPA possess the raw data?

Why have the data not been made available to registrants affected by the Agency’s actions or in response to FOIA requests?

If no:

Why not? How does this lack of possession and lack of availability of the data not conflict with the 2009 Presidential memorandum which says that if scientific and technical information is developed and used by the Federal Government, it should ordinarily be made available to the public? [“... mandating disclosure of scientific and technical information developed and used by the Federal government.”]

Why is the Agency not complying then with the goal of that memorandum for transparency in the use of scientific information in policy making?

How can EPA say that its use of epidemiology data for chlorpyrifos is transparent when the Agency did not obtain and consider the underlying raw data for the studies it relied upon or provide minutes from the meeting with the researchers?

Without the raw data, how can the Agency confirm there is no negative data, null results or confounding factors that would have changed the Agency’s conclusions about the studies?

How is such a decision consistent with EPA’s reliance for chlorpyrifos risk assessment 2 purposes on epidemiology studies for which the Agency cannot obtain and consider the raw data?

EPA says that it is relying on “uncertainty” created by the epidemiology studies to set the FQPA additional safety factor for chlorpyrifos. But hasn’t EPA created this uncertainty by failing to obtain and consider the raw data for the epidemiology studies the Agency is relying upon?

**EPA Response:** The EPA provided funding for the Columbia Center for Children’s Environmental Health (CCCEH), the Mount Sinai Center for Children’s Environmental Health and Disease Prevention Research, and Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) cohort at the Center for Environmental Research and Children’s Health (CERCH). The EPA and the National Institute of Environmental Health Sciences (NIEHS) jointly provided funding to the CCCEH under the 1997 and 2003 Request for Applications (RFAs). The approximate EPA funding for the 5 year CCCEH awards was \$3.9 million under the 1997 RFA (matched by NIEHS) and \$3.6 million under the 2003 RFA (NIEHS provided \$3.5 million).

Similarly, the EPA and the NIEHS jointly provided funding to the Mount Sinai Center for Children’s Environmental Health and Disease Prevention Research under the 1997 and 2003 RFAs. The approximate EPA funding for the 5 year Center awards was \$3.9 million under the 1997 RFA and \$4.0 million under the 2003 RFA (matched by the NIEHS with \$4.1 million under the 1997 RFA and \$3.8 million under the 2003 RFA).

The EPA and the NIEHS also jointly provided funding to the CERCH under the 1997, 2003, and 2009 RFAs. The approximate EPA funding for the 5 year Center awards was \$4.5 million under the 1997 RFA (NIEHS provided \$4.2 million), \$3.6 million under the 2003 RFA (NIEHS provided \$3.3 million), and \$3.6 million under the 2009 FRA (NIEHS provided \$4.2 million).

In the summer of 2015, Dr. Dana Barr of Emory University provided the agency with limited raw urine and blood data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful for the agency’s current purpose of assessing risk to chlorpyrifos. The files provided from Dr. Barr do not contain the biomonitoring data from the key publications from CCCEH which describe associations between blood levels of chlorpyrifos and neurodevelopmental deficits in children. The EPA does not have any of the other measurements of the children in the cohort (e.g., chlorpyrifos blood data, interviews, test or IQ scores). The CCCEH researchers have not provided these data, asserting that the pesticide component of the cohort study was privately funded, not federally funded, and therefore disclosure of underlying data is not required. The agency received two FOIA requests specifically asking for raw data on the three U.S. children’s cohorts. For the first FOIA request, EPA-HQ-2016-002089, the requester was provided all the responsive records (i.e., the files provided by Dr. Barr) and the request was closed March 2, 2016. For the second request, EPA-HQ-2016-003947, the agency did not have any additional files beyond those provided for the first request. The second FOIA was closed on March 23, 2016.

While the EPA strives to ensure that data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

In the past, the EPA sought to obtain the original raw data used to support certain epidemiological analysis of *in utero* exposure to chlorpyrifos and subsequent adverse neurodevelopmental health outcomes in children generated by the CCCEH to support the human health risk assessment of chlorpyrifos. Prior to the 2013 meeting with CCCEH investigators, the EPA thought these data would be important to both clarify the exposure-response relationship observed in the epidemiology study relative to the current regulatory endpoint (acetylcholinesterase inhibition), and also to resolve uncertainties regarding study participants co-exposure to other environmental contaminants, among other areas of uncertainties. CCCEH researchers did not agree to provide these data; however, the researchers met with the EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist the EPA in resolving uncertainties. As a result of this meeting, the EPA concluded that access to the raw data would not provide answers to the EPA's questions. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, the EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties.

In the summer of 2015, the EPA again requested the raw data from Columbia University. The Columbia University investigators again denied the EPA's request. However, the investigators did provide additional summary information on the blood biomonitoring data. The agency has made this additional information publicly available. The EPA continues to engage with Columbia University on this topic.

**Conaway 39a.** Related to the use of these epidemiology studies, in 2011, EPA said that it was reviewing a Scientific Advisory Panel report regarding the Agency's Draft Epidemiology Framework and would, also during 2011, release a revised version of the framework for public comment.

Why has the Agency not completed this task?

**Conaway 39b.** How can the Agency's reliance on the Draft Epidemiology Framework to integrate the epidemiology studies into the risk assessment for chlorpyrifos be reasonable when, contrary to EPA's promise, the framework has not been revised consistent with SAP recommendations and made available for public comment?

**EPA Response to Conaway 39a and 39b:** Although use of epidemiology is common in other agency regulatory programs, epidemiology studies focusing on pesticides have only become available in the last few years. Thus, epidemiology data are less frequently used in evaluation of pesticides. The EPA decided that additional experience was needed in applying the “Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment” prior to its finalization. Obtaining such experience is consistent with the recommendations of the Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel (FIFRA SAP) (2010) to “conduct a broader analysis” to improve the written description of the process of integration of epidemiology with other lines such as animal toxicity data. The ongoing work on chlorpyrifos and the organophosphates are examples of such experience. The FIFRA SAP commended the agency for developing the draft Framework and was “impressed with the documentation presented.” The agency also notes that the FIFRA SAP was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data. Because the FIFRA SAP was basically supportive of the overall approach, the agency believes use of the draft Framework in its current form is appropriate prior to the finalization of the document.

**Conaway 39c.** What are the number and total cost of all of the animal studies conducted by registrants that EPA has required and/or evaluated over the years to assess the potential toxicity and health risks of the OP pesticides, for which the proposed reliance on the three controversial epidemiology studies would trump, invalidate, or dismiss all of the animal study results?

**EPA Response:** The EPA has established data requirements (40 CFR) so that the agency can conduct appropriate risk assessments, including risks to human health. The relevant studies are associated with the toxicological data requirements for a food use. There are generally 30 studies that may be required but some pesticides may have more studies and some may have fewer. The organophosphate (OP) pesticides typically have completed all of the required studies since their initial registration, through reregistration, and to date during registration review. The EPA does not know the cost of generating these data for any particular company or chemical.

The agency has not limited the number of studies reviewed to the three epidemiology cohorts. In fact, the agency has reviewed hundreds of studies from laboratory animals, cell systems (including human), biomonitoring, and epidemiology on a variety of scientific areas related to human health effects. These studies were evaluated together in a weight of evidence analysis.

**Conaway 39d.** What is the biological mechanism of toxicity that accounts for supposed differences between the controversial epidemiology studies and the mountain of reliable data from animal toxicology studies? What is the biological plausibility of the results observed and any conjectured mechanisms of action? What are all of the possible confounding factors that could affect, influence, or produce the results observed, and how

have they been accounted for in the reports that EPA has relied on? Who/what is/are the unexposed cohort that shows that the effects allegedly found in the controversial epidemiology studies could reasonably be attributable to pesticide exposure?

**EPA Response:** The EPA conducted detailed evaluations of the scientific literature on the neurodevelopmental potential of chlorpyrifos and other OPs as part of reviews by the FIFRA SAP in 2008 and 2012 along with the 2014 human health risk assessment for chlorpyrifos and the 2015 literature review for all the OPs. This includes review of registrant submitted studies along with studies from the scientific literature. Biological plausibility of the findings from the epidemiology studies are found in numerous studies conducted in laboratory animals and using new technologies, including human cells. There are a large number of animal studies using rats and mice from a dozen laboratories worldwide which have reported neurodevelopmental effects in offspring exposed to chlorpyrifos in the womb or after birth. Some *in vitro* studies, like those recommended by the NAS in the 2007 report on Toxicity in the 21<sup>st</sup> Century, conducted at very low concentrations have suggested several biological mechanisms which could underlie effects at low exposure levels as seen in the epidemiological studies.

These studies present strong evidence that developmental neurotoxicity of chlorpyrifos and other OPs may not be due to acetylcholinesterase inhibition *per se*, but to other actions on critical aspects of neuronal development. There are a number of biologically plausible molecular events proposed for chlorpyrifos and other OPs effects on the developing nervous system, with ongoing academic research pursuing many of these potential pathways. Some of the more promising mechanisms represent molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling) and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Overall, there is good evidence that neurodevelopmental effects may not be solely a function of acetylcholinesterase inhibition.

The EPA is including epidemiologic research results from three prospective birth cohort studies. These include: 1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University; 2) the Mt. Sinai Inner-City Toxicants, Child Growth and Development Study or the "Mt. Sinai Child Growth and Development Study;" and 3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California, Berkeley.

In these epidemiology studies, mother-infant pairs were recruited for the purpose of studying the potential health effects of environmental exposures during pregnancy on subsequent child development. Each of these cohorts evaluated the association between prenatal chlorpyrifos or OPs exposure with adverse neurodevelopmental outcomes in children through age 7 years and to limited extent up to 11 years old. The CCCEH Mother's and Newborn study and the Mt. Sinai Child Growth and Development study participants were likely exposed to chlorpyrifos and other OPs through the diet and

through residential use of the pesticide for indoor pest control. The CHAMACOS cohort participants were employed as farm laborers or were residing in homes with farm laborers. The CHAMACOS study participants likely experienced exposure to OPs through the diet and from occupational exposure (primarily inhalation and dermal routes), as well as probable indirect take-home exposures.

Biomonitoring data were collected from individuals within each cohort. The unexposed children in the epidemiology studies are those whose biomonitoring data are low and often below the limit of detection, i.e., so low as to not be measurable. The unexposed children are derived from the same populations and location in the same living and economic conditions as the exposed or highly exposed children. In this way, important issues such as socioeconomic status are similar across the entire group of exposed and unexposed.

The EPA focused its review on research results from these three epidemiological cohort studies due to the considerable strengths in study design, conduct, and analyses. Investigators from each study cohort utilized a strong study design (prospective birth cohort), measured pesticide exposure using several different methods including biomarkers, and measured neurodevelopment effects in children using well-established assessment tools in both clinical and research settings. In addition, the investigators have accounted for potentially confounding variables including socio-economic status and other environmental exposures. Evaluation of these confounding variables is important to reduce the chances of a false positive study result. Across these cohort studies, investigators collected relevant information on demographic characteristics and other environmental exposures and used this information in the statistical analysis. Other environmental exposures considered by the investigators were blood lead, environmental tobacco smoke, polycyclic aromatic hydrocarbons (PAHs), methylmercury, or other non-OPs. The EPA and the FIFRA SAP (2008 and 2012) believe that the cohort study authors were able to appropriately measure and model the effect of potential confounding variables on the study outcomes.

The agency held another meeting of the FIFRA SAP on April 19-21, 2016 to review a new analysis using the blood biomonitoring data from the Columbia University epidemiology study.

**Conaway 39e.** Given the pesticide uses registered today, what is the relevance of the pesticide exposures that allegedly caused effects observed in the controversial epidemiology studies to the current regulatory picture?

**EPA Response:** Agricultural use of OPs remain today for many crops across the United States. Agricultural workers (including women who may be pregnant) who mix, load, and/or apply pesticides, as well as those who work in previously treated fields (e.g., harvesting citrus fruit) are exposed to high levels of OPs. In addition, some areas of the country are predicted to have OPs or their more toxic degradates in drinking water. Exposure to OPs through food to the entire country is also expected.

**Conaway 39f.** Please explain in layman's terms the process for "\*Systematic Review of scientific literature for laboratory animal studies & epidemiology studies" used by the Agency. How does this differ from the Agency's review of studies and data it requires registrants to conduct and submit in support of pesticide registrations? How do the two processes supplement, complement, or contradict each other?

[<http://www.epa.gov/sites/production/files/2015-10/documents/op-risk-assessment-approach.pdf>. Also <https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html>]

**EPA Response:** In recent years, the National Academies' National Research Council (NRC) has encouraged the agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making (NRC 2011, 2014). The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" (NRC 2014). According to the NRC, systematic reviews "have several common elements: transparent and explicitly documented methods, consistent and critical evaluation of all relevant literature, application of a standardized approach for grading the strength of evidence, and clear and consistent summative language."

The EPA's approach to reviewing scientific data include: data collection, data review, and integration procedures. Therefore, the agency's standard review approaches for assessing toxicology data submitted by registrants and for integrating the registrant supported data with information from the open literature are consistent with the NRC's recommendations for systematic review. As such, although the terminology may differ, the approaches are consistent and similar.

**Conaway 39g.** With such a requirement for an extensive base of these studies, how, according to your own Framework, does the Agency weigh an epidemiology study that is not conducted to the same standards as that required for a registrant study and where you do not even have in your possession the raw data?

**EPA Response:** Most laboratory animal studies submitted to the agency by the registrants follow the EPA and Organisation for Economic Co-operation and Development (OECD) guidelines and thus have specific and defined study designs. Epidemiology studies do not have such OECD guidelines; moreover, epidemiology studies can vary significantly in their study design.

The EPA developed a "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" in 2010 which was reviewed by the FIFRA SAP and received public comment. The Panel commended the agency for developing the draft Framework and was "impressed with the documentation presented." The agency also notes that the Panel was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data.

In the draft Framework, the agency describes several areas for consideration of the quality of epidemiology studies: exposure assessment, confounding factors, statistical analysis, potential bias in observational research, interpretation of null studies, external validity (generalizability). The SAP concurred with these identified scientific areas for consideration and suggested additional ones including sample size and associated statistical power, and outcome assessment. The EPA has assessed all of these considerations as part of the evaluation for chlorpyrifos and the OPs. The EPA focused its review for OPs on research results from the three epidemiological cohort studies due to the considerable strengths in study design, conduct, and analyses demonstrated in these investigations. Investigators from each study cohort utilized a similarly strong study design (prospective birth cohort); measured pesticide exposure using several different methods including environmental indicators as well as specific and non-specific biomarkers of chlorpyrifos; ascertained developmental outcomes using validated assessment tools well-established in both clinical and research settings; and, measured, analyzed, selected and statistically adjusted for potentially confounding variables including socio-economic status and other environmental exposures using reasonable and appropriate methods.

The EPA believes the draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization. Similarly, the EPA's draft Framework is consistent with recommendations from the NRC in its 2009 report on *Science and Decisions*<sup>3</sup> that describes the importance of using problem formulation at the beginning of a complex scientific analysis.

**Conaway 39h.** From 1996 when FQPA was enacted through the current date, EPA has made multiple, specific formal findings based on extensive reliable databases that FQPA safety factors for OP insecticides can be reduced or eliminated. The Agency has proceeded to regulate the uses of these pesticides in the marketplace on that basis, and has therefore determined that the residue tolerances are safe. FFDCA §408(b)(2)(A)(1) requires the Administrator to "... modify or revoke a tolerance if the Administrator determines it is not safe." What specific determination have you now made that the chlorpyrifos tolerances are "not safe"?

**EPA Response:** The EPA periodically reviews existing registered pesticides to ensure they can be used safely, without unreasonable risks to human health and the environment. The periodic review of pesticide registrations is required by FIFRA. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. The EPA will review each registered

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<sup>3</sup> NRC (National Research Council). (2009). *Science and decisions: Advancing risk assessment*. Washington, DC: The National Academies Press. [http://www.nap.edu/openbook.php?record\\_id=12209](http://www.nap.edu/openbook.php?record_id=12209)

pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

As part of registration review, the EPA assesses any changes that have occurred since the last registration decision to determine whether the pesticide still satisfies the statutory standard for registration. The EPA considers any new data or information on the pesticide and decides whether a new risk assessment must be conducted. In the case of chlorpyrifos and the OPs, many of the epidemiology studies, mechanistic studies, and laboratory animal studies on the neurodevelopmental effects of OPs were published after reregistration was completed in 2006. As such, there is significant new information relevant to the human health effects of this group of pesticides which require a re-analysis of scientific information relevant for the FQPA Safety Factor.

As section 408(b)(2)(C) of the FFDCA instructs the EPA, in making its “reasonable certainty of no harm” finding, that in “the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children.” Section 408 (b)(2)(C) further states that “the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.” Given the totality of the evidence, there is sufficient uncertainty in the human dose-response relationship for neurodevelopmental effects which prevents the agency from reducing or removing the statutory 10X FQPA Safety Factor.

**Conaway 40.** For the chlorpyrifos risk assessment, the Office of Pesticide Programs conducted a highly refined dietary assessment for possible residues on food and found no risks of concerns. Why then does the Agency rely on only an unrefined, screening level assessment to claim risks from drinking water as the basis for the Proposed Rule?

**EPA Response:** The December 2014 drinking water assessment conducted by the EPA is a refined, higher tier assessment that examined potential exposure to chlorpyrifos and its transformation product, chlorpyrifos-oxon, at a national and a regional scale in order to locate where concentrations in drinking water may be of concern. The assessment followed a tiered approach, investigating not only maximum pesticide label rates, but also lower rates to identify uses and watersheds that would not be expected to be problematic. The uses that exceeded the drinking water level of concern in the regional analysis were further explored, e.g., evaluating exposure on a watershed basis. This “proof of concept” example showed an overlap of potential chlorpyrifos use sites that may result in an exceedance of the drinking water level of concern with watersheds that supply source water for community drinking water systems. The exercise demonstrated that chlorpyrifos applications result in variable drinking water exposures that are highly localized and that the highest exposures generally occur in small hydrologic regions where there is a high percent cropped area on which chlorpyrifos use could occur.

The EPA finished a regional analysis for two regions of the country, the Pacific Northwest and South Atlantic-Gulf, to demonstrate the feasibility of this methodology and to solicit public comment on the approach. The EPA is currently finalizing the regional assessment for the remaining regions of the United States. In addition to the refined spatial scale at which the analysis was completed, two additional aspects of this drinking water assessment that contribute to its complexity and sophistication are the incorporation of surface water monitoring data and drinking water treatment effects. Results of surface water monitoring are presented and compared to model-estimated concentrations. This analysis showed that when modeling scenarios are parameterized to reflect reported use and estimated drinking water concentrations are adjusted to reflect percent cropped area, the estimated modeled concentrations are within an order of magnitude of the measured concentrations reported in the monitoring data. Finally, typical water treatment processes were considered in predicting residues in finished drinking water.

**Conaway 41a.** The EPA has stated that its drinking water assessment for chlorpyrifos is incomplete. Has the Agency ever before based a proposed tolerance revocation on an incomplete drinking water assessment?

**EPA Response:** The national scale drinking water assessment for chlorpyrifos was completed in 2014 and showed that many uses at maximum label rates and rates lower than maximum would result in concentrations exceeding the drinking water level of concern. Because of these results, further analysis was conducted to look at the spatial distribution of estimated drinking water concentrations at a regional scale. This exercise is a higher level refinement and not generally completed or required for most pesticides. As such, the EPA finished a regional analysis for two regions of the country, the Pacific Northwest and South Atlantic-Gulf, to demonstrate the feasibility of this methodology and to solicit public comment on the approach. The EPA is currently finalizing the regional assessment for the remaining regions of the United States.

**Conaway 41b.** While the Agency reached this high level of refinement for the food dietary assessment since the passage of FQPA in 1996, why has the Agency not reached a comparable level of refinement in their assessment methodologies for drinking water over that same time period of 20 years?

**EPA Response:** The level of sophistication of the EPA's drinking water assessments has greatly improved over the past 20 years. Drinking water assessments, including the assessment conducted for chlorpyrifos, now include the ability to account for the impact of different soils, agronomic practices, meteorological data, application methods and timing, buffers, volatility, and application technology, just to name a few areas where our modeling capabilities have improved. Current drinking water assessments also better account for the percentage of community drinking water intake watersheds that could be treated by the pesticide and drinking water treatment effects. Monitoring data, when available, also plays a larger role in our ability to predict and characterize pesticide concentrations under actual use conditions.

**Conaway 41c.** Since the Agency has had that much time to refine their drinking water assessment methodology, why then is there a rush to decision on chlorpyrifos?

**EPA Response:** The chlorpyrifos drinking water assessment is highly refined and incorporates all currently available data and methodologies for predicting exposure through drinking water. The timeline for decision making was set by the U.S. Court of Appeals for the Ninth Circuit.

**Conaway 41d.** Why does the agency refuse to use reliable data from tens of thousands of water monitoring samples for chlorpyrifos and other pesticides, and instead insist on using modeling procedures that are not validated by data, and produce conflicting conclusions?

**EPA Response:** The EPA uses mathematical models as well as monitoring data to generate exposure estimates for drinking water and aquatic exposure assessments. Modeling and monitoring data are both important tools that provide different types of information that can be used for assessing pesticide concentrations in water. Models calculate estimated drinking water concentrations using laboratory data that describe how fast a pesticide breaks down to other chemicals and how it moves in the environment. In addition, modeling provides an efficient tool for exploring the impact of different environmental factors such as soil type and meteorological conditions on estimated pesticide concentrations in water. Although computer modeling provides an indirect estimate of pesticide concentrations, these concentrations can be estimated continuously over long periods of time, and for places that are of most interest for a particular pesticide. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak concentrations from infrequent, large storms (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>).

Monitoring data provide snapshots of pesticide concentrations in time at specific locations. When the monitoring sites reflect areas that have a likelihood of pesticide occurrence in water (based on pesticide use as well as local runoff or leaching vulnerability), when sampling occurs during the time frame in which pesticides are expected to be used, and when the sampling is frequent enough to estimate exposures for the endpoints of concern, it is more likely that the EPA will be able to incorporate that data quantitatively. Monitoring data will typically underestimate upper bound or peak concentrations due to insufficient sampling frequency. While this is more of a concern for surface water monitoring, it can still be a consideration for groundwater monitoring. Therefore, monitoring data often are expected to provide a lower bound estimate of exposure for purposes of risk assessment. Statistical methods are being developed to address the uncertainty in estimating upper bound pesticide concentrations from monitoring data.

Often, sampling frequency and location are limiting factors in comparing monitoring results to modeling or in using monitoring data quantitatively. However, monitoring data can also be valuable in adding context to the exposure assessments. For instance,

detections of a given pesticide can provide a measure of a lower bound of exposure. While the data may not be robust enough to ensure a high-end exposure has been observed, the detections do indicate that transport has occurred in the study. At a minimum, qualitative data can provide a balance against modeled estimates and can be useful for characterization of risk conclusions.

The EPA uses all reliable laboratory and field/monitoring data to assess pesticide exposure in drinking water. In the case of chlorpyrifos, water monitoring data from the U.S. Geological Survey (USGS) National Water-Quality Assessment Program (NAWQA), USEPA/USGS Pilot Reservoir Monitoring Program, USDA Pesticide Data Program (PDP), and California Department of Pesticide Regulation (CDPR) were evaluated in the 2011 preliminary drinking water assessment with reference to an acute exposure to chlorpyrifos and its degradation product chlorpyrifos-oxon. For the 2014 assessment, additional water monitoring data from Washington State Department of Ecology and Agriculture (WSDE/WSDA) Cooperative Surface Water Monitoring Program, Dow AgroSciences (Orestimba Creek), and Oregon Department of Environmental Quality were evaluated and presented as part of the drinking water assessment update.

Additionally, model simulations were completed to represent two different water monitoring datasets - WSDE/WSDA and Orestimba Creek. For both of these water monitoring programs, enough information was available, including chlorpyrifos use information, as well as the percent cropped area, to parameterize the model. In these simulations, the modeled concentrations were within an order of magnitude of the measured concentrations. This suggests that the modeling results are not overly conservative and provide reliable estimates in the absence of all the necessary information to put monitoring results into proper context.

**Conaway 42a.** The Agency has publicly advocated for harmonization in tolerances among trading partner countries.

Why has EPA taken the step of this Proposed Rule with no agreement among other countries and seemingly no evaluation of or concern about potential impact on trade?

**EPA Response:** In making its tolerance decisions, the EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. However, the EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe. The timing of this proposal is the result of a U.S. Court of Appeals for the 9<sup>th</sup> Circuit Court order to respond to that petition by October 31, 2015. This proposal also implements the agency findings made during the registration review process required by section 3(g) of FIFRA (7 U.S.C. 136(a)(g)) which the EPA is conducting in parallel with its petition response. That process requires the EPA to re-evaluate existing pesticides every 15 years to determine whether such pesticides meet the FIFRA registration standard set forth in FIFRA section 3(c)(5), 7 U.S.C. 136a(c)(5). In part, that standard requires the EPA to ensure that dietary risks from the pesticide meet the FFDCA section 408 safety standard. Section 408 directs

that the EPA may establish or leave in effect a tolerance for pesticide only if it finds that the tolerance is safe, and the EPA must revoke or modify tolerances determined to be unsafe (FFDCA 408(b)(2)(A)(i)). Section 408(b)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” In its Revised Human Health Risk Assessment, the EPA determined some exposures to chlorpyrifos may be unsafe. The Revised Human Health Risk Assessment is available at [www.regulations.gov](http://www.regulations.gov) in the chlorpyrifos docket (EPA-HQ-OPP-2008-0850-0195).

**Conaway 42b.** What is your obligation under the World Trade Organization Sanitary Phytosanitary Agreement (WTO SPS) in this respect, and how has it been fulfilled?

**EPA Response:** The EPA ensures that its tolerance decisions are in keeping with the World Trade Organization's Sanitary and Phytosanitary Measures Agreement. Consistent with that agreement, the effective date the EPA is proposing for the revocation of chlorpyrifos tolerances in the proposed rule ensures that the tolerances will remain in effect for a period sufficient to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. The EPA plans to issue a notice by the fall of 2016 with updates to part of its risk assessment, including a refined drinking water assessment. With the issuance of the notice, the EPA will notify the WTO and ask for further comment on the proposed rule and underlying science. The EPA will consider WTO's comments prior to issuing a final decision.

**Conaway 43.** By establishing a policy of “no net loss” for natural resources, doesn't the Presidential Memorandum: Mitigating Impacts on Natural Resources from Development and Encouraging Related Private Investment change how NEPA operates by requiring agencies to avoid, minimize, and fully mitigate impacts to natural resources? Will EPA follow the policies of the memorandum in the NEPA process? Is it correct that NEPA does not “mandate protection of the environment,” but requires impacts to be identified? By establishing a policy of “no net loss” for natural resources, doesn't the Presidential Memorandum change the function of NEPA by requiring agencies to authorize only actions that avoid, minimize, and fully mitigate impacts to natural resources?

**EPA Response:** The EPA and other federal agencies have extensive experience consistently implementing the provisions of the National Environmental Policy Act (NEPA) while working to achieve a “no net loss” of natural resources goal. The administration established a nationwide “no net loss” of wetlands goal in 1989, for example, that has been very successful in reducing annual conversion and destruction of wetlands without changing the operation of NEPA. The EPA is confident, based on our experience, that the new Presidential Mitigation Memorandum does not alter the way NEPA has traditionally been implemented or change its basic function.

**Ranking Member Collin Peterson, Minnesota**

**Peterson 1.** The EPA has been reviewing biogenetic carbon-dioxide emissions for a few years now and it's seemed to come to a head with the Clean Power Plan. My

understanding is that under the current framework for biogenetic carbon-dioxide, agricultural residue is treated the same as fossil fuels in Clean Power Plan compliance, unless it's sustainably grown. Using agricultural residues for energy production, bioproducts, and biofuels already happens. We want our farmers to be a part of the solution and I'm a bit perplexed how grown plants are treated the same as fossil fuels. Can you explain the current framework the EPA is using to assess biogenetic carbon-dioxide emissions? And are you consulting with USDA in regard to determining "sustainably grown" so our farmers can participate?

**EPA Response:** On February 9, 2016, the Supreme Court granted a motion to stay the Clean Power Plan (CPP). As a result of that action, states are not currently required to submit a state plan or a request for extension by September 6, 2016.

In the final CPP, states have the flexibility to choose whether or not to allow affected sources to use biomass as a compliance option to meet their emission standards. The CPP gives states the flexibility to describe the types of biomass that are being proposed for use under their state plans, how those proposed feedstocks or feedstock categories should be considered as "qualified biomass" (i.e., a biomass feedstock that is demonstrated as a method to control increases of CO<sub>2</sub> levels in the atmosphere), and explain the proposed valuation of biogenic CO<sub>2</sub> emissions.

The EPA generally acknowledges the CO<sub>2</sub> and climate policy benefits of waste-derived biogenic feedstocks and certain forest- and agriculture-derived industrial byproduct feedstocks. The final rule also provides that states may use agricultural and forest biomass feedstocks if they adequately demonstrate that the use of such feedstocks appropriately controls increases of CO<sub>2</sub> levels in the atmosphere.

As part of the EPA's effort to advance the technical understanding of the role of biomass in addressing greenhouse gas emissions, in November 2014, the EPA released the second draft of its scientific report, Framework for Assessing Biogenic Carbon Dioxide for Stationary Sources. The revised report takes into account Science Advisory Board peer review recommendations on the 2011 Draft Framework, as well as the latest information from the scientific community and other stakeholders. The EPA developed the revised Framework as a policy-neutral framework for assessing biogenic CO<sub>2</sub> emissions from stationary sources – it was not developed as technical guidance in conjunction with any specific policy or program. The EPA's continued refinements of the Framework will parallel the EPA's consideration of biomass in the context of its policies and programs.

As in the case of other scientific and policy processes, for biomass topics we consult with relevant experts, such as our colleagues at USDA, states, stakeholders, and academic and research scientists to provide information and examples of existing and potential programs recognized as carbon-beneficial and therefore possible approaches to achieving the goals articulated in the President's Climate Action Plan.

**Peterson 2.** I was contacted by an ag procession plant in my district and discovered that not only do plants have to have an OSHA worker protection plan, but apparently EPA

also requires a worker protection plan. And now with the Food Security Modernization Act (FSMA), there will be a third requirement that will also involve worker training. Is there any coordination between OSHA and DPA in regard to what these worker protection plans encompass? Is there flexibility for plants to use one plan to cover both requirements? OR do they literally have to have two separate plans?

**EPA Response:** First, to the extent that these concerns with the Agricultural Worker Protection Standard (WPS) rule were raised in regard to an agricultural processing plant, please note that post-harvest uses of pesticides are excepted from the requirements of the WPS (170.303(b)(5)), so the WPS does not apply to the use of pesticides in agricultural processing plants and such processing plants are not otherwise affected by the WPS.

Second, the WPS also does not require a written worker protection plan. Employers only need to comply with the provisions of the rule, but are not required to develop a written plan describing how they will meet the requirements of the rule. The EPA has also coordinated with the Occupational Safety and Health Administration to ensure there is not overlap of our regulations.

***Congressman Ted Yoho, Florida***

**Yoho 1.** Administrator McCarthy, it is my understanding that on October 27, 2015, FOIA request EPA-HQ-2016-000771 was submitted to EPA. This FOIA requests copies of communication from 2011 to the present between the U.S. Environmental Protection Agency, U.S. Food and Drug Administration and U.S. Department of Agriculture related to the biopesticide active ingredient Banda de Luinua albus doce (BLAD) and the end use product Problad Plus (EPA Registration Number 84876-1 ). It is my understanding no information related to this request has been provided or released to date. Can you explain any reasons for this delay? Can you provide an expected timeline when information should be released?"

**EPA Response:** The EPA responded to request EPA-HQ-2016-000771 and sent all requested records. This FOIA request is closed.

***Congressman Jeff Denham, California***

**Denham 1.** The National Association of Clean Air Agencies testified to EPA that the new 2015 ozone standard "will have a profound impact on the work of the state and local air pollution control agencies." This is troubling, especially considering many of these same agencies are still working on the 2008 ozone standard, which has yet to be fully implemented.

Given its geographical layout and persistent droughts, California's Central Valley has had to expend exceptionally more resources to keep up with every reaching air standards.

What type of assurance is the EPA giving our states and local governments, municipalities, and businesses that the EPA is not setting them up to fail by constantly moving the clean air goalpost?

**EPA Response:** The EPA and state co-regulators share a long history of managing ozone air quality under the Clean Air Act (CAA), underpinned by a wealth of previously issued EPA rules and guidance. The overall framework and policy approach reflected in the implementing regulations for the 2008 ozone standards provide an effective and appropriate template for the general approach states would follow in planning for attainment of the revised 2015 ozone NAAQS. In particular for California areas where the state and districts are still actively working toward attaining the 2008 ozone NAAQS, the EPA is committed to continue helping these air agencies identify and take advantage of potential planning and emissions control efficiencies that may occur within the horizon for attaining the 2015 standards. Following past precedent, the EPA intends to propose revoking the 2008 standards and provide transition rules intended to help avoid any potential inefficiencies as states begin implementing the Clean Air Act's requirements for the 2015 standards.

**Denham 2.** Taking into account EPA's accidental release of farm information to environmental activist groups in 2013, farmers and ranchers in my district are understandably concerned about the lack of data security measures preventing the EPA from collecting superfluous farm information.

In light of the 2013 incident – as well as other highly damaging breaches into OPM and DOD – what improvements has the EPA made, or is the EPA making, to ensure it only collects the information it needs, and that such information is secure?

**EPA Response:** The EPA is continually working to improve its processes for collecting and managing data related to environmental protection programs. For example, the EPA recently established through rulemaking the minimum set of NPDES program data based on the EPA's current reporting requirements (see Appendix A to 40 CFR Part 127). During the development of this rulemaking, the EPA carefully considered input from authorized state programs, provided in comments and meetings, to match the minimum set of NPDES program data to the existing regulations and practice, including how these data are currently used by the EPA and authorized state programs. The EPA and states streamlined the NPDES electronic reporting requirements down to the minimum number of data elements needed to oversee management of the NPDES programs in the most efficient manner possible

In addition, due to comments received during the NPDES Electronic Reporting Rule [see: Comment Response Document for the NPDES Electronic Reporting Rule (Final Rule), EPA-HQ-OECA-2009-0274-0575, available at: <http://www.regulations.gov>], the EPA is masking facility specific information for unpermitted CAFOs that are not in violation of the CWA, responding to particular privacy concerns raised regarding operators living in close proximity to these facilities.

More broadly, the EPA is taking steps to improve the agency's information security posture and meet the Administration's cybersecurity cross-agency priority goals. The EPA improved the use of strong authentication for logging onto the EPA network,

improved anti-phishing protections, and coordinated with the Department of Homeland Security to improve asset and vulnerability management and malware defenses.

**Denham 3.** Your agency's honeybee acute toxicity proposal could restrict the use of over 3,000 crop protection products when a grower has contracted for pollination services. These products are primarily derived from 76 Active Ingredients. How did EPA decide on these Active Ingredients? Were risk assessments and benefits analysis conducted, as is required by law, before this proposal was published?

**EPA Response:** *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* is aimed at providing greater protection to bees where acute risk is presumed to be the highest, namely when certain exposure (i.e., contract pollination scenarios) and presence of an acutely toxic pesticide coincide. For this proposed risk mitigation strategy, the agency focused only on a subset of compounds identified as highly toxic to bees, which are likely to have the greatest adverse effect on bees. The 76 active ingredients are those that have been determined via testing to have an acute contact toxicity value less than 11 micrograms per bee, based on data required to be submitted by pesticide registrants. Limiting our focus to these compounds was intended to gain the greatest benefits of protection to bees with the least impact to growers. The agency will assess each compound under the registration review program, with a more thorough and robust data set as identified in our *Risk Assessment Framework for Pollinators*. As a result, additional chemical-specific, risk-based labeling will be developed based upon the results of these subsequent assessments.

As part of its planning and analysis prior to issuing the proposal, the EPA considered the potential cost to growers. The agency is currently reviewing the wide range of comments it received in response to the proposal and is considering how to proceed. Based upon the comments received, we are developing options on moving forward. Throughout this process, the agency continues to weigh both the level of protection to bees, and the potential cost to growers.

**Denham 4.** I'm sure you're aware of the advances residue-detecting technologies have made, with some being able to detect parts-per-billion. With this kind of preciseness, a tolerance-restricted pesticide could be found on an unrelated crop in a negligible but detectable amount, say by way of cross breezes or other unintentional factors. Is EPA taking this into consideration, to ensure that incidents such as these do not condemn an entire crop?

**EPA Response:** The EPA is aware of the issues associated with the stated concern and note that enforcement questions related to the presence in or on food of a pesticide chemical residue for which there is no established EPA tolerance or tolerance exemption is under the purview of the U.S. Food and Drug Administration (FDA), not the EPA. Questions regarding the FDA's practices with respect to testing and enforcement activities related to low level pesticide chemical residues found in or on food should be directed to the FDA.

**Denham 5.** Some special interest groups have been demanding that the EPA now operate outside its existing FIFRA scope and regulate pre-treated seeds. Given that there is still no solid scientific evidence to necessitate a change in oversight does the EPA intend to continue respecting this distinction?

**EPA Response:** With respect to the litigation filed by public interest groups, on March 14, 2016, the EPA filed a motion with the district court in the Northern District of California to dismiss the case against the EPA. A hearing on this motion was held on May 12, 2016, and the following day the court issued an order deferring a decision on the merits of the EPA's motion to dismiss until the EPA produced an administrative record. The EPA has complied with the court's order and expects the court to address its jurisdiction (the subject of the motion to dismiss) during summary judgment proceedings. Under the current litigation schedule, summary judgment motions are to be filed in September and should be argued in October 2016. Treated seeds that meet the requirements of the treated article exemption at 40 CFR Part 152.25(a) are exempt from regulation under FIFRA and the EPA has not proposed to amend that regulation.

**Congressman Chris Gibson, New York**

**Gibson 1.** The Hudson River Natural Resource Trustees -- USF&W and NOAA -- have publicly called for additional environmental dredging of the Hudson River Superfund site by GE and asked EPA to delay GE's decommissioning of its cleanup operations before certifying the cleanup as complete. Would EPA be willing to meet with these environmental leaders to discuss the agency's reasoning behind its Hudson River dredging decision?

**EPA Response:** The EPA has discussed the decommissioning of General Electric's sediment processing facility and other operations with the federal Natural Resource Trustees for the Hudson River. In particular, the U.S. Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration (NOAA) actively participate in meetings of the Hudson River Community Advisory Group (CAG), and both NOAA and FWS have taken part in CAG meetings at which the EPA explained its reasons for approving GE's facility decommissioning.

**Gibson 2.** According to my constituents, EPA responded in December 2015 to the Natural Resource Trustees' that the cleanup is inadequate and will not meet EPA's own goals. In this response to Hudson River environmental leaders, EPA Assistant Administrator Mathy Stanislaus and Regional Administrator Judith Enck agreed to an expedited 5-year review to determine whether the Hudson River Superfund cleanup has met its goals. The following month, R.A Enck published an Op-Ed in the Albany Times Union stating the cleanup has achieved its goals.

What will EPA do to ensure the 5-year review is conducted without bias, expeditiously in conformance with EPA guidance, and in a manner that ensures the input of the Trustees as equal partners and of the key environmental and other stakeholders?

**EPA Response:** The second five year review for the site is underway and is being conducted in accordance with the EPA guidance. The EPA is working closely with all stakeholders to ensure a thorough and unbiased five year review. The stakeholders, including the federal trustees, New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory Group (including non-governmental organizations) were invited by the EPA to participate on the Five Year Review team. Five Year Review team meetings are being held monthly through the fall.

**Gibson 3.** Is EPA considering any additional options that have not already been pursued to promote further clean-up and safeguarding of the Hudson River?

**EPA Response:** The second five year review is underway and the EPA is working closely with all stakeholders to ensure a thorough five year review. The stakeholders, including the federal trustees, the New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory Group (including nongovernmental organizations) were invited by the EPA to participate on the Five Year Review Team. The EPA supports the trustees' continuing efforts to safeguard the Hudson River and will continue to cooperate and communicate with federal and state natural resource trustees on the Hudson River remediation.

***Congressman Dan Newhouse, Washington***

**Newhouse 1.** Last year, a federal judge in Washington State ruled several dairies in my district were culpable of "open dumping" of manure under the Resources Conservation and Recovery Act – commonly referred to as RCRA – based solely on escalated nitrate levels in nearby wells. This is unprecedented for a number of reasons, but primarily that nitrates were ruled as a "solid waste" under RCRA. Especially given that EPA's regulations under RCRA find the definition of solid waste, "does not apply to agricultural wastes, including manures and crop residues, returned to the soil as fertilizers or soil conditioners." While there are environmental laws our nation's dairies are subject to – and that's a good thing – it seems clear to me that RCRA was not intended to be one of them. Administrator McCarthy, I would be interested to know if EPA has any desire or intent to revisit the regulations promulgated under RCRA based on this judge's misguided decision?

**EPA Response:** The EPA has no current plans to develop or issue regulations under the resource Conservation and Recovery Act related to animal feeding operations.

**Newhouse 2.** In the dairy RCRA decision, the judge said of USDA's Natural Resource and Conservation Service (NRCS) manure lagoon construction standards, that, "even assuming the [manure] lagoons were constructed pursuant to NRCS standards, these standards specifically allow for permeability and, thus, the lagoons are designed to leak." This is another reason why take such exception with this judge's decision, because in my experience in agriculture, I know that NRCS is the gold standard in technical assistance to farmers. Briefly, and generally, I was wondering if you could give your thoughts on

NRCS and your Administration's relationship with them. Do you have confidence in NRCS standards?

**EPA Response:** The EPA supports the goals of USDA's Natural Resources Conservation Service waste treatment lagoon standards providing that lagoons should be constructed, operated and maintained without polluting air or water resources; that additional measures should be considered to prevent a sudden breach or accidental release into surface water bodies, riparian areas, and critical habitat; and that additional measures of safety should be taken to prevent lagoon seepage into underlying shallow aquifers or aquifers that provide domestic water supplies.

**Newhouse 3.** Administrator McCarthy, as you are aware, Section 7 of the Endangered Species Act directs EPA to consult with Fish and Wildlife Services if a proposed action may impact an animal or plant listed as endangered. Over the past several years, EPA has been the target of lawsuits claiming it has failed to consult with Fish and Wildlife or the National Marine Fisheries Service on pesticide registration. In recent years, I understand your agency has been working with the Services on implementing a collaborative approach, and is piloting that approach on a handful of active pesticide ingredients undergoing review. While I appreciate that EPA is now trying to meet its consultation requirements, I am concerned that the initial draft reviews for the first three active ingredients considered under this pilot are approximately *3,000 pages each*. How do you expect this work to be productive or helpful to manufacturers, the farmers that use these products, or the species it's supposed to be protecting?

**EPA Response:** The EPA acknowledges there is a large amount of information posted in support of the pilot biological evaluations (BEs) for chlorpyrifos, diazinon and malathion. However, the background information that has been made available is the basis for the EPA's effects determination for all threatened and endangered species and designated critical habitat in the United States. The main sections, which include the problem formulation and exposure and effects characterization, are approximately 250-350 pages, and the remaining appendices and attachments include supplemental information that interested parties can refer to if they wish to see the underlying data for our analysis.

The EPA released the draft BEs for these three pesticides on April 6, 2016. On May 5, 2016, the EPA, Fish and Wildlife Service (FWS), National Marine Fisheries Service (NMFS), and USDA held a public webinar for all external stakeholders to discuss the process and interim scientific methods used to make effects determinations for the three pilot chemicals, including a roadmap on how to navigate the various sections, appendices, and attachments of the draft BEs. There were 189 attendees for the webinar.

The agencies recognize the need for further refinement of the interim scientific methods including an early screening step that effectively allows for a focus of resources on ESA-listed species and designated critical habitat where exposure to pesticides is likely to result in adverse direct and indirect effects. In addition, on June 29 and 30, 2016, the agencies held a two day workshop to offer a forum for stakeholder suggestions for

refining some of the interim scientific methods used in the draft BEs. 105 attended the workshop in person and 58 more over the phone.

**Newhouse 4.** In the 2014 Farm Bill, there was a requirement directing the EPA, Fish and Wildlife, and National Marine Fisheries provide two reports updating our Committee on the progress of developing a workable approach on collaborative ESA consideration in pesticide registration. We did receive one of those reports in November 2014, but the second one is long overdue. Do you have a sense of when we might expect that next report?

**EPA Response:** The agencies are currently working on the second Report to Congress and expect to provide this final report by the end of 2016.

**Newhouse 5.** Administrator McCarthy, you testified at the hearing that EPA is working closely with the businesses and the regulated community on how Washington States new water quality standards will be implemented. However, it was my understanding that, the regional administrator and regional manager for the Office and Water and Watersheds told a broad coalition of business and industry early in the process that EPA was unwilling to negotiate the fish consumption rate or cancer risk level. Can you tell me specifically what has EPA done to work with the regulated communities in Region 10 and Maine on human health criteria?

**EPA Response:** The EPA has met with industry representatives (as well as environmentalists, tribes, and local governments) on many occasions to discuss water quality standards designed to protect public health in the Pacific Northwest. Additionally the EPA Region 1 Regional Administrator held an open conference call for interested stakeholders to discuss Maine WQS in February 2015. In all of these discussions, the EPA has been clear that it is our preference that states develop water quality standards to protect the state's designated uses for its waters (e.g., fishing, swimming) using the best available science.

**Newhouse 6.** For thirty years or more, EPA, FDA, and the best available science have concluded that there is essentially no additional risk of cancer at exposures based on risk levels of  $10^{-6}$  as applied to the exposure of the general population (in the case of water quality standards a fish consumption rate) as long as the average consumption rate for more high exposed populations does not create a risk of more than  $10^{-4}$ . What scientific human health research has EPA developed or relied on to conclude that in Maine, Oregon, Idaho and Washington that high tribal consumption rates must be protected to  $10^{-6}$ ?

**EPA Response:** The EPA encourages states to consider local and regional data when it is available in developing water quality standards that protect the uses of its waters such as for fishing. In many areas of the country, such as in Maine, Oregon, Idaho and Washington, tribes have protected treaty rights that provide for reserved fishing rights. Additionally local and regional data show that these tribal members consume much more fish. In Maine, the Wabanaki study shows rates of tribal fish consumption from 286

grams per day to over 500 grams per day. In the northwestern states there are several fish consumption surveys that show that tribal fish consumption rates over 1,000 grams per day. To provide for the federal treaty rights of these tribal members, the EPA expects states to consider these site-specific higher fish consumption rates as well as a  $10^{-6}$  cancer risk.

**Newhouse 7.** EPA and other federal agencies have long considered standards that protect within the range of risk levels of  $10^{-6}$  to  $10^{-4}$  to represent a *de minimis* risk of incurring cancer. What scientific research has EPA developed or relied on to conclude that  $10^{-6}$  is now an upper bound risk level for the protection of public health?

**EPA Response:** The EPA considers  $10^{-6}$  as a *de minimis* risk level but allows states to choose higher risk levels to protect their populations. However, treaties in Washington envision fish free from contaminants. To comply with these tribal treaty rights,  $10^{-6}$  is a close approximation of a *de minimis* level of risk. The  $10^{-6}$  risk level is appropriate when the EPA or states take treaty rights into consideration when developing water quality standards.

**Newhouse 8.** EPA has stated numerous times over many administrations—including in its 2000 Human Health Methodology – that there is no real difference between  $10^{-6}$  and  $10^{-5}$  in terms of risk management, as long as more highly exposed populations are protected to  $10^{-4}$ . It is easy to understand why, as it is the difference between a theoretical additional risk of one millionth of a percent (0.000001%) and one hundred thousand of percent (0.00001%). Even at a risk level of  $10^{-4}$ , the additional risk over an entire lifetime is an additional on ten thousandth of a percent (0.0001%). This is why federal agencies, including EPA, have long considered these risk levels to represent the equivalent of no additional risk of additional cancers. If EPA applied its current and long-standing risk management guidance to Washington State, we would expect no new cases of cancer based on exposure to waters meeting the standards. Imposing more stringent risk management levels, reinventing a new zero, would provide no additional benefit to public health. What scientific research has EPA developed or relied on to conclude that risk levels of  $10^{-6}$  and  $10^{-5}$  no longer represented essentially the same level of risk? What scientific research has EPA developed or relied on to conclude that water quality standards now require a more stringent application of risk levels in developing water quality standards?

**EPA Response:** The EPA's use of a  $10^{-6}$  cancer risk level is a risk management decision, which EPA considers appropriate for the general population. It is important to note that when developing the 2000 Human Health Methodology for deriving numeric water quality criteria, identified in your question, we undertook a review of language from other agency mandates (e.g., The Clean Air Act, the Food Quality Protection Act) and believe the target of a  $10^{-6}$  risk level is consistent with agencywide practice. While the Methodology presents a range of acceptable cancer risk levels for the general population, states and authorized tribes are specifically encouraged to consider highly exposed population groups when determining a protective cancer risk level including, in the case

of the State of Washington, taking into account the important principles of treaty rights and environmental justice.

**Newhouse 9.** Throughout the Pacific Northwest, background concentrations of PCBs and Arsenic exceed the criteria EPA has proposed for Washington State, and the criteria that EPA has advised in comments should be developed by Idaho and Washington. Can EPA provide an analysis of impact its proposed PCB and arsenic criteria would have on section 303(d) listings of impaired water bodies, and what those listings would mean under the prohibition of new expanded discharge until the criteria are met? Can EPA provide an economic impact analysis of the impact its proposed PCB criteria will have on private and public facilities that hold NPDES permits and on permitted stormwater discharges?

**EPA Response:** The EPA evaluated the potential costs to NPDES dischargers, and the potential for incremental water body impairments, associated with state implementation of the EPA's proposed criteria. This analysis is contained in the record for the EPA's proposed rule for the State of Washington. Since the proposed rule was published, the EPA obtained additional water quality monitoring data from the State Department of Ecology's Environmental Information Management database for PCBs and will identify additional potential incremental impairments, if any, in any revised economic analysis that the EPA develops for the State of Washington.

**Newhouse 10.** The economic impact analysis EPA provided with its proposed rule in Washington State represents that there was no surface water data that indicated ambient concentrations of PCBs above the EPA proposed criteria. The Washington State Department of Ecology has published studies showing that all of Puget Sound and its major tributaries, including the Strait of Juan de Fuca, have PCB levels above the EPA proposed criteria. Can EPA explain why this data was not considered in its economic impact analysis? Has EPA identified treatment technologies that can achieve the proposed PCB criteria? If so, what does it cost to install and operate those technologies?

**EPA Response:** Since preparing the economic analysis for the proposed rule, the EPA has obtained additional PCB monitoring data and will analyze these data and report the potential incremental impairment results, if any, in any revised economic analysis that the EPA develops for the State of Washington. Currently, the quantification limit in the State of Washington for PCBs is 0.1 µg/L, which is several orders of magnitude greater than the proposed revised criteria of 0.0000073 µg/L for freshwater and marine waters.

**Newhouse 11.** EPA's scientists have consistently stated that a Probabilistic Risk Assessment (PRA) approach represent the more advanced and better scientific approach to risk assessment. Why isn't EPA using a PRA approach to develop water quality criteria and other standards? Does the Agency have plans to move to that approach, considering its commitment to using the best science, and if so, when would that take place?

**EPA Response:** The EPA is evaluating current probabilistic risk assessment approaches to water quality standards in the literature. As of now, no states have submitted human health criteria based on such an approach.

***Congressman Sean Patrick Maloney, New York***

**Maloney 1.** Currently, hundreds of residents in my district lack access to a clean water source as a result of contaminated groundwater from the Hopewell Precision superfund site. Thankfully, after years of effort, a solution is at hand. The EPA is working with stakeholders to finalize the design of infrastructure that will connect the impacted homes to a viable water source. I appreciate the real progress that we've made on this issue, and want to recognize EPA Region II Administrator Judith Enck for her tireless work on this. Ultimately though, successful completion of the project will require funding from the EPA.

I ask you that you fully fund this project, and do all you can to ensure that those impacted finally get the access to a clean water source. I also ask that you work with my office on this priority, and let me know how I can help make sure this gets done.

**EPA Response:** The EPA anticipates the decision to fund the site should be made this fiscal year. While the costs of the entire cleanup of the Hopewell Precision Site will not be fully funded this year, it is anticipated that the full cost of the cleanup will be funded over several budget cycles which will not impact the multi-year schedule for completion. The first stage of work is hiring a contractor, which will take several months from the initiation of funding.

**Maloney 2.** As you know, the EPA has been overseeing General Electric's work to remove Polychlorinated biphenyls (PCBs) from the Hudson River. I appreciate the significant progress that the EPA and GE have made in this effort in the last few years. But I am concerned that unless further action is taken there is a significant risk that an unacceptable level of PCBs could remain in the Hudson.

In December 2015, my office helped to facilitate a meeting between the EPA and local stakeholders to address those concerns. I appreciate that the EPA took the time to meet with us. I was extremely gratified to see the EPA announce in the wake of the meeting its intent to conduct an expedited 5-year review of the Hudson River, to determine what further actions will be necessary.

Can you please confirm that the EPA still plans on conducting an expedited 5-year review? If so, what is the anticipated timeline? I ask that you ensure that the review occurs in a manner that allows for a thorough, science-based approach. Successful completion of this review is vital to ensuring the long-term health of the Hudson River and its watershed.

I also ask that you meet with me and local stakeholders so we can speak with you about this issue and share with you our thoughts on how we can best cooperate on the shared goal of a clean, healthy Hudson River.

**EPA Response:** The second five year review for the site is underway and is being conducted in accordance with the EPA guidance. The EPA is working closely with all stakeholders to ensure a thorough and unbiased five year review. The stakeholders, including the federal trustees, New York State Department of Environmental Conservation and Department of Health, and representatives of the Community Advisory Group (including non-governmental organizations) were invited by the EPA to participate on the Five Year Review team. Five Year Review team meetings are being held monthly through the fall.

***Congresswoman Suzan DelBene, Washington***

**DelBene 1.** Last September, the EPA published Interim Recommendations for environmental standards and ecolabels for use in federal procurement. EPA's recommendation for lumber excludes several standards that are widely used in the United States, including the Sustainable Forestry Initiative (SFI) and American Tree Farm System (ATFS) standards, which represent 70% of the certified acres in the U.S and 95% of the certified acres in Washington State. EPA has signaled that this recommendation is mandatory for federal procurement. Under what circumstances may a federal procurement officer purchase wood products that do not meet this FSC requirement, such as those certified to SFI or ATFS? And, given the significant volume of sustainably harvested timber that may be excluded from federal purchasing, please explain the process for EPA amending this recommendation in the future.

**EPA Response:** Under Executive Order 13693 - *Planning for Federal Sustainability in the Next Decade* – the EPA issued recommendations to assist federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A-119, and related federal policies that guide the EPA's use of voluntary consensus standards and private sector conformity assessment activities. In addition, the EPA continues its progress with piloting the Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement, and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we develop these recommendations. The agency issued Federal Register Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.<sup>4</sup> Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations. As such, FAR Case 20 15-033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when it will be available to the public, are viewable at [http://www.acq.osd.mil/dpap/dars/far\\_case\\_status.html](http://www.acq.osd.mil/dpap/dars/far_case_status.html).

**DelBene 2.** What actions has the EPA taken to educate organic and conventional pesticide users about biopesticides?

**EPA Response:** The EPA is committed to encouraging the development and use of low-risk biopesticides as alternatives to conventional chemical pesticides. In 1994, the EPA created the Biopesticides and Pollution Prevention Division (BPPD) and specifically focused it on raising the profile of biopesticides and helping them get licensed. BPPD, in the Office of Chemical Safety and Pollution Prevention – Office of Pesticide Programs, is responsible for regulatory activities associated with biologically-based pesticides, and is recognized as the international authority on biopesticides. In partnership with USDA and the IR-4 Specialty/Minor Crop Project at Rutgers University, the EPA supported 88 projects through the Biopesticide Demonstration Grant Program. From 2004-2010, the program invested more than \$1.3 million to research the efficacy of biopesticides for specialty and minor crops.

The EPA is actively working with growers and grower organizations interested in using biopesticides. Our intent is to ensure growers have the information they need to incorporate biopesticides into their pest management programs.

In recent years, the EPA has attended several food producer and marketer meetings that have included representatives of small fruit and vegetable growers. The EPA is establishing relationships with these stakeholders to provide them with information on the benefits offered by biopesticides.

Additionally, the EPA is implementing a biopesticide strategy that includes developing case studies on biopesticide successes, especially instances in which biopesticides have offset conventional pesticide use without negatively impacting grower costs.

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<sup>4</sup> Federal Register Notice, February 27, 2014, “Draft Guidelines for Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement” (79 FR 11102). <https://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04329.pdf>

Federal Register Notice, March 19, 2015, “Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement” (80 FR 14372). <https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06275.pdf>

**DelBene 3.** As the number of biopesticide registration actions has increased, has EPA directed any additional resources to the Biopesticide and Pollution Prevention Division? What steps has EPA made or is EPA planning to take to ensure biopesticide Pesticide Registration Improvement Act (PRIA) timeframes are met and to reduce the number of biopesticide renegotiations?

**EPA Response:** In recent years, the EPA has provided additional staffing resources to help address the growing number of registration requests for biopesticides.

Over the past five years, the EPA reduced the renegotiation rate from 61.6 percent in Fiscal Year (FY) 2010 to 18 percent in FY 2015. At this point in FY 2016, the renegotiate rate is approximately 14.6 percent, which is lower than the rate for conventional pesticides. We have achieved these reductions through a number of measures:

- More thorough screening of applications upon submission to ensure that they meet the outlined criteria for completeness at the beginning of the review process;
- Identification of registration package deficiencies early in the review process. This allows time for companies to fix packages without having to renegotiate; and
- At industry's request, providing training seminars for registrants and consultants to help ensure packages are submitted correctly.

***Congresswoman Vicky Hartzler, Missouri***

The following questions relate to the agency's Worker Protection Standards (WPS) rule [40 CFR 170 *et seq.*] which was signed by the Administrator on September 28, 2015 and published in the Federal Register on November 2, 2015

**Statutory Requirements**

Section 25(a)(2)(B) of FIFRA (7 U.S.C. 136w (a)(2)(B)) states: "At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation."

Section 25(a)(3) (7 U.S.C. 136w (a)(3)) of FIFRA also states: "At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate."

Questions:

**Hartzler 1.** Please state for the record the date on which EPA provided to the Secretary of Agriculture the final copy of the WPS rule that was signed on September 28, 2015.

**EPA Response:** The EPA sent the draft final Worker Protection Standard rule to the Secretary of Agriculture on May 13, 2015. This draft final rule did not include provisions for authorized or designated representatives. After further deliberations, the EPA decided to restore these provisions, with certain limitations and modifications. The EPA provided the revised draft final rule to USDA on June 22, 2015. As required under section 25(a)(2)(D) of FIFRA, the EPA announced the notification to the Secretary of Agriculture for this review in the Federal Register (80 FR 28838, May 20, 2015).

**Hartzler 2.** Please state for the record the date on which EPA provided to the House Committee on Agriculture the final copy of the WPS rule that was signed on September 28, 2015.

**EPA Response:** As required under section 25(a)(3) of FIFRA, the EPA sent the pre-promulgation draft of the final rule to the U.S. House of Representative's Committee on Agriculture and to the U.S. Senate's Committee on Agriculture, Nutrition, and Forestry on May 14, 2015. In addition, as required under the Congressional Review Act (5 U.S.C. 801 *et seq.*), the EPA submitted a report containing the final copy of the rule that was signed on September 28, 2015, and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States on October 9, 2015.

**Hartzler 3.** The WPS rule (40 CFR 170.311) grants a designated representative the right to certain pesticide information used on a farm upon presentation of a written, signed authorization by a worker. Please answer the following questions related to this provision.

With a letter to the House Agriculture Committee from Assistant Administrator Jim Jones dated May 12, 2015 Mr. Jones enclosed a "draft final rule revising and updating the agricultural Worker Protection Standard." Please cite the section of the rule submitted to the Committee on May 12, 2015 that contains language granting either to "authorized representatives" or "designated representatives" access to farm-specific pesticide information.

**EPA Response:** The May 12, 2015 draft final rule did not include provisions for authorized or designated representatives. The proposed rule, published March 19, 2014, included provisions relating to authorized representatives in the draft sections 170.5 and 170.11(b)(2) and on pages 15479-15480 of the preamble a discussion of the provisions, but as of May 12, 2015, the EPA was not intending to finalize those provisions. After further deliberations, the EPA decided to restore these provisions, with certain limitations and modifications. The EPA provided the revised draft final rule to USDA on June 22, 2015. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the final version of the rule was submitted to Congress on October 9, 2015.

**Hartzler 4.** Please provide to the committee copies of any comments, including emails, memos or other documents, submitted to EPA from the US Department of Agriculture or

other executive department offices, including the White House, that relate to the original proposed provision relating to “authorized representative” and to the provision in the final rule relating to “designated representative.”

**EPA Response:** USDA’s comments, and the EPA’s responses to the proposed rule and the final rule, are included in the public docket as part of the Executive Order documentation, and those comments and responses related to the authorized representative and the designated representative are available from under docket ID EPA-HQ-OPP-2011-0184.<sup>5</sup> This provision was not an area of significant deliberation during the interagency review process for this rulemaking.

**Hartzler 5a.** In the final WPS rule (Federal Register, page 67513, November 2, 2015), EPA states that it “has been convinced by comments in support to retain the option for a designated representative.”

Please provide the Committee copies of the comments to which the agency refers in the Federal Register notice.

**EPA Response:** The EPA received a significant number of comments in support of and in opposition to retaining the proposal for the designated or authorized representative. Few of the comments presented new information or information substantially different from that known to the EPA at the time the proposed rule was published, and as a result, the comments – both pro and con – collectively convinced EPA that it was correct in its initial opinion that a designated representative provision is reasonable and appropriate. However, some commenters provided recommendations that appear to be appropriate remedies for legitimate concerns about the proposed requirement. The EPA reconsidered the proposed option and alternatives, and concluded that retaining the option for a worker to designate a representative was necessary for their ability to access pesticide hazard information, but specified in more detail the requirements for designating a representative and for a designated representative’s request information. See 40 CFR Part 170.311(b)(9).

Although the EPA considers the collective comments – pro and con – as confirming the agency’s decision to include a designated representative provision in the WPS, the comments below in support of the designated representative option for enhancing access to pesticide hazard communications information provide additional insight.

- Migrant Clinicians Network<sup>6</sup>
- Farmworker Advocacy Network<sup>7</sup>
- American Public Health Association<sup>8</sup>
- Florida Legal Services<sup>9</sup>

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<sup>5</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2520>

<sup>6</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2291>

<sup>7</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2250>

<sup>8</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-1846>

<sup>9</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-2166>

- Telamon Corporation<sup>10</sup>

**Hartzler 5b.** Were any of the comments received by the agency after the close of the comment period?

**EPA Response:** Some comments were received after the comment period closed. All were included in the docket, regardless of the date they were submitted; and were considered in developing the final rule. These comments received after the close of the comment period were not significantly different and did not raise issues or present new information than those submitted by the close of the comment period.

**Hartzler 5c.** Were any of these comments the result of *ex parte* communications? Please supply copies of those comments?

**EPA Response:** All comments related to the Worker Protection Standard rulemaking received by the EPA during the period between proposal and publication of the final rule were added to the docket, where they became a matter of public record available for review (except for those portions of comments submitted under business confidentiality claims or containing personal privacy information). Written comments appear in the docket as submitted.

**Hartzler 6a.** The Federal Register notice of November 2, 2015 says that “EPA is unaware of issues related to worker representatives in those states.” [referring to Texas and California].

Please provide the Committee with any analysis or documents used by EPA in analyzing the Texas and California provisions.

**EPA Response:** The only documents the EPA reviewed related to the Texas and California provisions were the regulations for Texas and California related to agricultural worker representatives.

The Texas Agricultural Hazard Communication Act at ([http://www.statutes.egis.state.tx.us/\\_Docs/AG/htm/AG.125.htm](http://www.statutes.egis.state.tx.us/_Docs/AG/htm/AG.125.htm)) establishes procedures for the designated representative’s access to information about hazardous chemicals to improve the health and safety of agricultural workers. In addition, Texas provided comments on the proposed rule related to the provision, noting that the requirement to provide the information should coincide with the record retention schedule and should be in writing.

The California Code of Regulations, Sections 6723 and 6761 at (<http://www.cdpr.ca.gov/docs/legbills/calcode/subchpte.htm#a0303>), establish requirements for employers to provide, upon request from an employee representative, access to any records or documents required to be maintained under the regulation.

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<sup>10</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0184-0179>

**Hartzler 6b.** Please provide the Committee any documents or analysis prepared or utilized by EPA that demonstrates that the Texas and California provisions have directly resulted in greater worker safety.

**EPA Response:** The EPA is not aware of any documents or analyses that assess improvements in worker safety as a direct result of these provisions.

**Hartzler 7.** Please provide the Committee with documents or memoranda it used to analyze the OSHA regulation and its applicability in requiring similar provisions in an agricultural setting.

**EPA Response:** The EPA considered the requirements of the U.S. Occupational Safety and Health Administration's regulation at 29 USC section 1910.1020 ([https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10027](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10027)), and believes similar requirements should apply to agriculture. As cited in the preamble to the proposed Worker Protection Standard (March 19, 2014), in adopting the Hazard Communication Standard (HCS), OSHA stated there was evidence to indicate potential for chemical exposure in every type of industry, and that lack of knowledge about those hazardous chemicals puts employees at significant risk of experiencing material impairment of health (52 FR 31852; August 24, 1987;)(59 FR 6126; February 9, 1994). The OSHA rule applies to general industries, maritime, and construction employers who are responsible for records of employee exposure to toxic substances or harmful physical agents, among other requirements, but expressly does not apply to agricultural employers per 29 CFR Part 1928.21(b). The OSHA rule requires that the employer provide to the designated representative (or requesting employee) access to the employee's exposure record upon their request, in a reasonable time, place, and manner.

The Worker Protection Standard requires agricultural employers to maintain pesticide application records and Safety Data Sheets when workers are on the establishment. These records provide the exposure and hazard information, parallel to those required under OSHA's rules for other industries. Farmworkers, in terms of demographics, are similar to construction workers, in that their jobs may be short term, of low economic status; and they may be low literacy and non-English speaking. The EPA believes that agricultural production can comply with these requirements with little disruption. The EPA recognizes that a significant number of workers face disadvantages that can reasonably make them reluctant to ask their employers for information related to their pesticide exposure, and finds that access to the information through a designated representative, similar to the requirement in OSHA's HCS, is feasible and appropriate to protect worker safety.

**Hartler 8.** Does the authorization from the worker to the designated representative need to be notarized?

**EPA Response:** The authorization does not need to be notarized.

**Hartzler 9.** Once a farmer is presented with a written, signed authorization, does the farmer have a legal obligation to provide the information?

**EPA Response:** Under the Worker Protection Standard, the designated representative authorization must also be accompanied by a request letter containing certain information. If a valid designated representative authorization is accompanied by a valid request for information required by the WPS to be provided, then the farmer does have a legal obligation to provide only the information required by the rule.

**Hartzler 10.** Once the designated representative has the information, are there restrictions on what the designated representative may do with the information? (If so, please cite the section of the regulation restricting use of the information.)

**EPA Response:** The Worker Protection Standard does not place restrictions on what the farmworker or designated representative may do with the information.

**Hartzler 11.** Once the designated representative has obtained the information from the farmer, does the designated representative have any obligation to transmit or share that information with the worker who authorized access to the information? (If so, please cite the section of the regulation.)

**EPA Response:** The Worker Protection Standard does not impose on the farmworker or designated representative any obligation to transmit or share that information with the worker who authorized access to the information.

**Hartzler 12a.** The section of the WPS immediately preceding that related to designated representatives (§170.309(8)) states that “any treating medical personnel or any person acting under the supervision of treating medical personnel” may request pertinent information and may do so either orally or in writing. Thus, it appears that the access granted to designated representatives serves a purpose other than providing for the medical treatment of a worker who has been exposed to a pesticide.

What purposes, other than those related to the health or exposure of a worker to a pesticide, does §170.309(9) serve?

**EPA Response:** Workers and handlers may be reluctant to request the information for themselves due to their inability to communicate effectively with, or fear of, their employer, or because they may not be able to understand the information without help. The required information can be of value to workers before medical care is sought: First, having information available in non-emergency situations could help workers be aware of symptoms before they occur, help them avoid exposure, and possibly enhance the reporting of illnesses. Second, having access to the required information in advance of any medical need means emergency medical personnel would not have to lose critical time tracking down information instead of treating the ill or injured person. Third, having information available in non-emergency situations could help workers be aware of

symptoms of chronic illnesses, potentially enabling them to seek treatment earlier in the course of the illness.

Because of the potential burden to agricultural employers, the rule does not require that the required pesticide application information and Safety Data Sheets that provide the hazard information must be provided in any language other than English, although many farmworkers and pesticide handlers are not literate in English or even their native languages. Therefore there are potentially many circumstances these individuals could need the assistance of a designated representative to have “meaningful access” to the information such as having it translated in order to be able to make use of the information. Additionally, many farmworkers could be limited in their ability to get transportation back to an employer’s establishment after employment but would need the assistance of a designated representative to access the information they desire.

**Hartzler 12b.** Please cite EPA’s statutory authority to require a farmer to grant access to third parties for proprietary pesticide information when that access is not related to worker safety?

**EPA Response:** As discussed in the response to the previous question, the ability for a worker or handler to have meaningful access to the required pesticide application and hazard information is very much related to worker safety. In the 1992 rule, and continued in this revision, access to exposure information and first aid and other medical information is required for medical personnel in cases of injury or illness. For the reasons cited above the worker may not be able to access or make use of the information provided and would need a designated representative to get meaningful access to that information in order to understand the hazards of the chemicals he/she is working around, be better able to protect themselves, recognize potential signs of exposure or illness, and know how to respond appropriately if needed. The EPA’s statutory authority to establish requirements to protect worker safety is outlined in the rule and derives from FIFRA’s mandate to prevent unreasonable adverse effects on “the environment”, which FIFRA section 2(j) defines as including humans. Agricultural workers are clearly part of “the environment” for purposes of FIFRA, as discussed in U.S. Senate. S. Rep. No. 92-883 (Part II), 92<sup>nd</sup> Congress, 2<sup>nd</sup> Session at 43-46 (1972). U.S. Code Congressional and Administrative News 1972, p. 4063.

**Hartzler 13a.** §170.305 of the regulation states that a “*designated representative* means any persons designated in writing by a worker or handler to exercise a right of access on behalf of the worker or handler to request and obtain a copy of the pesticide application and hazard information required by §170.309(h) in accordance with §170.311(b) of this part.”

Are there any provisions in the WPS restricting who may be a designated representative? (If so, please cite the section of the regulation.)

**EPA Response:** There are no restrictions on who may be a designated representative.

**Hartzler 13b.** Would the WPS permit organizations like anti-pesticide activist groups to serve as designated representatives?

**EPA Response:** Any person or organization can serve as the designated representative if they have been properly designated in writing and the request conforms to section 170.311(b)(9).

**Hartzler 14.** If a designated representative had information related to pesticide use on a farm and wished to publish that information broadly, are there provisions in the WPS to prevent that from happening? (If so, please cite the section of the regulation)

**EPA Response:** The Worker Protection Standard does not include provisions that would prevent a farmworker or designated representative from publishing the information required under section 170.309(h).

**Hartzler 15.** If a designated representative had gained information related to pesticide use on a farm through a written declaration authorized under §170.311(b) and wanted to use that information publicly to exert pressure on a farmer to stop the farmer from using that pesticide, are there provisions in the WPS to prevent that from happening? (If so, please cite the provision)

**EPA Response:** The Worker Protection Standard does not include provisions that would prevent a farmworker or designated representative from using the information required under section 170.309(h) publicly.

**Hartzler 16a.** Many hired workers in agriculture – by most estimates more than 50% of the hired labor force – work in agriculture by presenting documents that contain false names, social security numbers, green cards or other information. An employer, such as a farmer, is legally required to accept such documents if they appear to be genuine. Because of this fact, it may be possible for an individual to present himself or herself to a farmer claiming to be a designated representative for a worker with a name that does not appear on the farmer's records. If the designated representative states that the individual worker did work on the farm but under a different name, what is the farmer's legal obligation?

Is the farmer's legally obliged to release the pesticide information? (If not, please cite the section of the regulation releasing the farmer from legal responsibility)

**EPA Response:** Where a person claiming to be a designated representative presents the name of a worker or handler that does not appear on the employer's records, the employer could refuse to provide the requested information unless other evidence, documentation or information known to the employer reasonably supports a conclusion that the worker or handler being represented by the designated representative was actually employed on the establishment.

**Hartzler 16b.** If the farmer does not release the information, is the farmer protected under the WPS? (Please cite the specific provision).

**EPA Response:** Yes. If a designated representative's request for information does not meet the requirements of section 170.311(b)(9), an employer's refusal to provide the requested information would not be a violation of FIFRA.

**Hartzler 16c.** If a designated representative has been found to be abusing this provision of the WPS, what sanctions would that individual face? (Please cite the specific provisions)

**EPA Response:** The Worker Protection Standard does not include provisions that would provide sanctions against a designated representative.

**Hartzler 17.** Given the concerns that have been raised by the agriculture community over the designated representative provision, would EPA be willing to suspend implementation of the provision and revise it after consultation with representatives of the agricultural community and re-proposing it in the Federal Register?

**EPA Response:** The EPA included a representative access provision in the proposed rule, specifically requested comment on potential problems it could cause (79 FR 15444, 15479), and received many pertinent comments from a broad range of commenters, few of which identified likely problems that were significantly different from those contemplated by the EPA at the time of proposal. The EPA does not expect that an additional comment period would produce significantly different information, but in any case, any person who has such information may submit it at any time for the EPA to review.

If the agency is presented with evidence that this provision of the rule is creating undue burden for the agricultural community, or the provision is being abused by certain designated representatives, the agency will consider whether the evidence warrants regulatory action in response. However, the EPA does not believe there are sufficient grounds for changing the rule at this time.

***Congressman Trent Kelly, Mississippi***

**Kelly 1.** Three years ago, a coalition of Mississippi beekeepers and farmers came together to identify how they could work collaboratively and do their part in tackling some of the bee health concerns. After numerous meetings and conversations this group ultimately concluded that agricultural pesticide exposure had little impact on honeybee health in Mississippi but instead factors like varroa mites and the diseases they carry were much bigger issues, which need to be addressed. However, this coalition did acknowledge that communication between beekeepers and farmers would further reduce the risk of pesticide exposure and the group decided to launch a voluntary effort called the Mississippi Bee Stewardship Program. The goal of this program was to enhance communication and cooperation between our state's beekeepers and agricultural pesticide applicators. This stewardship program encompasses a pragmatic set of best management

practices which deal with things like hive placement on the farm, identification of hive locations, and pesticide applicators being aware of the presence of foraging bees. A "bee awareness" flag was even designed to help people on the farm know where bees are located. This program has energized the agricultural industry in Mississippi and has created a more cooperative environment among beekeepers and farmers. The coalition I referred to earlier is now in the process of conducting assessments to determine the effectiveness of the enhanced communication with the hope that it has reduced and will continue to reduce pesticide exposure to bees.

Last summer, the White House commissioned a federal Task Force to focus on developing policy initiatives that would lead to improved pollinator health. Among the initiatives highlighted in the Task Force's report, included efforts to deal with habitat loss and additional research on pollinator parasites and diseases, and more local efforts to manage relationship between farmers and beekeepers, which was the interest in supporting the development of "state managed pollinator protection plans." The Mississippi Bee Stewardship Program has been held up nationally as a model of the desired state management plan approach and our state's department of agriculture should commended for taking this more flexible approach that collaboration rather than going in a more prescriptive, one-size-fits-all, direction.

Unfortunately, following the greater sense of good will and collaboration that was formed between beekeepers and farmers through the development of the Mississippi Bee Stewardship Program, recent actions by EPA in regard to key chemistries that farmers rely upon (Sulfoxaflor, or Tranform®) and further attacks on imidacloprid and seed treatments are beginning to undermine those relationships. Growers and beekeepers in Mississippi thought that they had addressed their pesticide/managed pollinator issues and could see the path forward but now I am hearing about concerns from many of my farm constituents about losing or diminished access to key pesticide products due to EPA's interest in protecting managed honeybees.

These products are vital to the protection against devastating pests that threaten farmers' crops and livelihood. The announcements and proposals from EPA are creating concerns in the relationships between farmers and beekeepers and will result in less collaboration in the future. It is perceived that the loss of these key crop protection products is the result of numerous lawsuits or environmental activists' claims over the process that EPA utilizes in the data collection and pesticide registration & review process. In addition, I am hearing from individual beekeepers in my state that have major concerns that if the farmers lose these key chemistries and are forced to sustain a major economic loss, they will not have a place to host their bees on the farms, thus creating a domino economic effect on the beekeepers as well.

Recently, we were notified that farmers are beginning to tell beekeepers they cannot host bees on the farm in Mississippi due to concerns and frustrations that key products to protect their crop are being taken away by EPA from the threats and frivolous lawsuits filed by beekeepers and environmental groups. This is of great concern to me. In this situation, EPA's responses to claims and pressure from a fraction of the beekeeping

industry and challenges from environmental groups is going to ultimately harm innocent beekeepers and find them with no farm to host their bees, driving wedge in the positive relationships that have developed over the last several years and impacting the beekeeper's ability to make a living.

Many of these beekeepers are not a part of the national beekeeper groups and do not have their perspective represented or heard. What further outreach to beekeepers that host bees on farms and farmers is EPA planning in order to discuss these concerns? My office would be happy to facilitate these conversations.

**EPA Response:** The question well describes the complex stakeholder dynamics, conflicting agendas, and cautions regarding both the vocal and silent voices that makes pollinator protection and pesticide use a challenging issue. The EPA also understands the concern about existing and new chemistries and their importance to both growers and beekeepers.

The agency agrees that the Mississippi State Plan, and the work done in Mississippi between growers and beekeepers, is a model. Indeed, the Mississippi State Plan, the North Dakota State Plan, and several others, were the first to demonstrate that a local response to the issue of pollinator protection was the best way to match the needs and resources of the local community with this issue. That work formed the basis for developing the efforts around Managed Pollinator Protection Plans (MP3s).

In March 2016, the EPA, in collaboration with USDA, the National Association of State Departments of Agriculture and the Honey Bee Health Coalition, held a two day symposium on MP3s. The Symposium was designed to bring together a wide range of stakeholders in order to share the tools, insights and relationships necessary for states, tribal and other stakeholders to pursue the development of MP3 plans effectively and efficiently.

Because MP3s are locally based, reflecting those that live and work in a state or tribe, they serve as a forum for state and local stakeholders to participate. The EPA has been encouraging and emphasizing communication between growers and beekeepers as a key component of MP3s. As another component of MP3s, the EPA and USDA are also working with the National Integrated Pest Management (IPM) Center to investigate and promote commodity-based, and/or local-based best management practices that balance pollinator protection and crop production. The National IPM Center will work with State IPM Coordinators to identify crop/pesticide/pollinator needs and support them through information development and dissemination.

Through continued work to evaluate and develop MP3s, the EPA intends to support the states and tribes in identifying their needs and finding solutions for pollinator protection and crop production.

***Congressman Mike Bost, Illinois***

**Bost 1.** Resistance Management is a critical concern for all farmers. Corn farmers have experienced increasing resistance problems with using traited corn. Resistance has developed in weeds, and pests like Corn Rootworm. Soil Applied Insecticides are registered by EPA for use on corn, including corn with traits, and have been proven effective in controlling rootworm and also improving yields. Is EPA planning to restrict the use of Soil Applied Pesticides with traited corn?

**EPA Response:** The EPA has not taken any regulatory actions to restrict the use of soil applied insecticides on corn. In response to signs of resistance to Bt traits in the corn rootworm, the EPA has developed new, more protective requirements designed to delay corn rootworm resistance to genetically engineered Bt corn. The EPA announced its new requirements in February 2016. As part of those requirements, the EPA is recommending against the use of soil applied insecticides for control of corn rootworm on corn rootworm traited corn except under limited circumstances and in consultations with experts. This recommendation is based on published scientific literature that indicates the use of soil applied insecticides for corn rootworm can present an additional resistance risk to Bt traits and on advice from the EPA's FIFRA Scientific Advisory Panel. Information and materials from this SAP meeting is available at <https://www.epa.gov/sap/meeting-materials-december-4-6-2013-scientific-advisory-panel>.

**Bost 2.** I am very concerned that EPA has not been coordinating with USDA on matters crucial to farmers and consumers regarding the importance of crop and environmental protection and on the economic benefits to farmers who use pesticides to protect their crop yields to feed America and the world. I understand that USDA has been willing to work with EPA. However, USDA is appropriately concerned about not being consulted about the calculation of the benefits provided to agriculture and farm production through the use of pesticides.

For example, the Chief Economist at USDA sent a letter on April 6, 2015, to EPA criticizing EPA for publishing an analysis on the economics of soybean production which USDA said was misleading, incomplete, incorrect, and that "as a whole USDA disagrees with the assessment."

The letter further said that "USDA is disappointed that EPA published the report . . . without offering USDA an opportunity . . . to correct the misrepresentations of economic costs and benefits that underlie this report." I certainly agree with USDA that USDA and EPA need to work together and note that federal regulations require that coordination or an opportunity for USDA to provide input to EPA if that determination would result in the suspension, cancellation, or change in classification of a pesticide.

In August, USDA sent a second letter to EPA, signed by Sheryl Kunickis, Director of the USDA Office of Pest Management Policy, saying that the May 29, 2015, EPA proposal on mandatory pesticide label requirements would be especially harmful to "numerous specialty crop farmers and the rural economics they contribute to across the U.S." USDA

was also concerned about the fact that the EPA “proposal has the potential to negatively impact . . . organic production . . . .”

Consultations between EPA and USDA are required in FIFRA in sections 2 (minor uses), 3 (minor uses), 4 (public health issues), and section 6 (suspensions, cancellations, imminent hazards; advance notice of EPA actions, and other FIFRA provisions mandate the opportunity for USDA input). Some consultations are required by regulation or OMB Circulars.

For all of 2015 and through the date of your response in 2016, can you please describe in appropriate detail consultations, discussions, and meetings EPA has conducted with USDA on the above examples on the following types of actions: determinations of economic benefits to farmers, including specialty crop farmers, regarding the use of specific pesticides; label requirements and changes; issues related to minor crops; public health matters; and the consideration of decisions to restrict, limit, cancel, or suspend the use of pesticides?

In your answers please include specific information including dates, participants, actions taken, and the outcome of those consultations, discussions, and meetings.

**EPA Response:** The following provides some examples of the discussions the EPA has had with USDA from January 1, 2015, through March 15, 2016. These consultations are summarized in the table below.

The EPA typically consults with USDA through the Office of Pest Management Policy (USDA-OPMP). OPMP then coordinates with other entities associated with USDA, including the Integrated Pest Management (IPM centers), as appropriate. For some reviews, therefore, the EPA is not in direct contact with all the participants. The EPA regularly coordinates and consults directly with USDA’s Animal and Plant Health Inspection Service’s (APHIS) Biotechnology Regulatory Services (BRS) on matters related to biotechnology and agriculture. Similarly, the EPA consults directly and regularly with Interregional Project 4 (IR-4) on matters related to uses of pesticides on minor crops (i.e., crops grown on less than 300,000 acres). In addition, for the past several years, the EPA has scheduled monthly meetings with OPMP to provide for coordination on a wide variety of pesticide regulatory matters.

The EPA and BRS coordinate on genetically-engineered (GE) crops which are resistant to herbicides and insects. In addition, EPA and BRS coordinate on GE microorganisms. The EPA has also coordinated closely with USDA-APHIS-BRS on the registration of herbicides containing rimsulfuron and nicosulfuron designed for use on Inzen sorghum (Inzen sorghum is a type of sorghum that is conventionally bred to be resistant to the effects of rimsulfuron and nicosulfuron herbicides). The registration of these herbicides could benefit sorghum growers who cultivate the Inzen sorghum line by providing improved weed control. Although Inzen sorghum is the product of conventional breeding and is not a GE crop, the EPA reached out to BRS. BRS assisted with an analysis which showed the potential for resistant trait conventionally bred into the sorghum to cross with

wild relatives which could become resistant to the herbicides that are proposed for use on Inzen sorghum and subsequently pose challenges to their control in agricultural production. The EPA issued these registrations on February 3, 2016.

USDA and HHS reviewed the EPA's assessment of an application for a new use of deltamethrin for the purpose of mosquito control. The review was led by USDA-OPMP (Office of Pest Management Policy), but the participating offices are not known. No comments were submitted. EPA found that the proposed use was a 'minor use' as defined by FIFRA 2(l)(2), 'lack of economic incentive.' As such, the registrant was eligible for a new period of exclusive use over the data submitted in support of the registration.

In addition to consultations over specific pesticides, the EPA engages with USDA over basic concepts that contribute, over time, to pesticide decisions. USDA also reviews rules proposed and finalized by EPA under FIFRA and as part of the inter-agency review coordinated by the Office of Management and Budget. For example:

- The EPA has been collaborating with USDA, as well as FWS and the National Marine Fisheries Service (NMFS) to develop interim scientific methods to assess the potential risks of pesticides to Federally endangered and threatened species and designated critical habitats, based on recommendations from the April 2013 National Academy of Sciences report, "Assessing Risks to Endangered and threatened Species from Pesticides." Specifically, USDA has provided expertise on pesticide uses for the draft pilot Biological Evaluation for diazinon and assistance with the use of the National Agricultural Statistics Service Cropland Data Layer to help define the footprint of agricultural use patterns;
- The EPA is in regular communication with USDA regarding biotechnology per the Federal Coordinated Framework for the Regulation of Biotechnology. For over 15 years, the EPA, USDA, and FDA have participated in monthly biotechnology calls where each agency shares regulatory updates, hot topics, and information on international activities. The EPA, FDA, and USDA-APHIS-BRS also have Memoranda of Understanding in place regarding coordination and information sharing as well as other MOU's associated with specific topic areas, e.g., coordination and collaboration on the potential environmental release of GE microorganisms. Additionally, through the Emerging Technologies Interagency Policy Coordination Committee, the EPA is working with USDA on updating the coordinated framework for biotechnology;
- For over three years, the EPA has been in regular communication with USDA-ARS regarding corn rootworm resistance management issues. During the corn growing season, the EPA participates in monthly conference calls with corn rootworm entomologists, including USDA researchers. The EPA received comments from USDA's OPMP (EPA-HQ-OPP-2014-0805-0076) in response to its solicitation for public comment on a corn rootworm mitigation strategy. The EPA modified its proposal to account for those comments and comments from others. Prior to releasing

the proposed draft strategy and prior to announcing an agreement in January 2016, the EPA communicated with OPMP to notify OPMP of the release;

- The EPA is consulting with USDA-ERS (Economic Research Service) to better understand the value of pollinators, especially managed honey bees, and how pesticide use may influence the habitat for wild pollinators. This information will help the EPA better characterize the risks pesticides pose to managed and wild pollinators;
- USDA reviewed the final rule to revise the Worker Protection Standard (WPS) and the proposed rule revising the standards for Certified Applicators. The review was coordinated by USDA-OPMP. The Animal and Plant Health Inspection Service (USDA-APHIS) and Forest Service (USDA-FS) participated significantly in the review of the Certified Applicators proposed rule; both entities run certification programs. An outcome of the discussion with USDA was that the EPA expanded the definition of farms and familial relationships eligible for the owner and immediate family exemptions to the WPS;
- The EPA and USDA have been coordinating closely for several years on the important issue of herbicide resistance. Weed resistance to herbicides has become a major economic and agronomic problem in U.S. agriculture in field crops such as corn, soybeans, cotton, and wheat, as well as minor and specialty crops. The EPA has proactively engaged USDA-OPMP and USDA-APHIS's Biotechnology Regulatory Service (APHIS-BRS) in this key area. This joint effort also includes the Weed Science Society of America (WSSA) and other stakeholders, where in 2012, WSSA published two special editions of their Journal of Weed Science that were the culmination of collaboration between EPA, USDA and WSSA. In addition to weed resistance to herbicides, the EPA is working with USDA and other stakeholders in efforts to manage insect and plant pathogen resistance to pesticides; and
- The EPA, USDA-OPMP, and USDA-APHIS-BRS have on several occasions participated jointly in a wide range of outreach and education efforts. In July 2015 the EPA and OPMP participated in a tour of herbicide-resistant weed problems in Iowa agriculture. Joining the group were weed scientists from the University of Kentucky and Iowa State University. In other outreach activities, USDA/OPMP joined EPA to discuss herbicide resistance and other issues of mutual interest at a meeting with the Commodity Research and Opportunities Partnership (CROP), an organization that represents corn, cotton, wheat, sorghum, and soybean growers.

While the EPA does not have detailed records of every consultation held with USDA regarding pesticide regulatory matters, the following table provides examples of the wide variety of interactions between the EPA and USDA over the past two years:

<b>Subject</b>	<b>Meeting Dates</b>	<b>Participants</b>
<i>Pesticide-specific consultations</i>		
Rimsulfuron and Nicosulfuron registrations on sorghum	January 29, 2015 February 27, 2015	USDA-APHIS-BRS
Sulfonylurea herbicides	May 27, 2015	USDA-OPMP
Deltamethrin minor use assessment	Draft reviewed by USDA and HHS, October-November, 2015	USDA-OPMP
Neonicotinoid insecticides	April 30, 2015, presentation by AgInfomatics on benefits	USDA-OPMP USDA-IR-4
<i>Endangered Species</i>		
Endangered Species Risk Assessments for Pesticides	Continued discussions from January 1, 2015 to present including bi-weekly conference calls and a week-long interagency workshop with EPA, FWS, and USFWS in January 2016	USDA-OPMP USDA-NASS
Federal Endangered Species Task Force (FESTF) meeting	July 14, 2015	USDA-OPMP USDA-NASS
<i>Biotechnology</i>		
Biotechnology Coordination Calls	Monthly for 15+ years	EPA, USDA, FDA
Discussion of USDA-FAS' mission, new breeding technologies and how the products may impact trade in agricultural commodities.	March 10, 2016	EPA, USDA-FAS
Biotechnonology MOUs	On-going discussions	EPA, USDA-APHIS-BRS
Working with USDA on the Emerging Technologies Interagency Policy Coordination Committee to update the coordinated framework for biotechnology	August 2015 and ongoing discussion	EPA, USDA-APHIS, USDA-OSEC
Corn Rootworm Resistance Management	Monthly during corn growing season for 3+ years	EPA, USDA ARS

<i>Pollinators</i>		
Value of pollinators	September 2, 2015, and on-going discussions	USDA-ERS
Pollinator habitat	December 1, 2015, and on-going discussions	USDA-ERS
Pollinator health task force	As needed since May 2014 (EPA and USDA co-chair the task force)	USDA-OSEC, USDA-OPMP, USDA-ARS, USDA-FSA, USDA-NRCS
<i>Rules</i>		
Worker Protection Standard revisions	May to July, 2015	USDA-OPMP
Certified Applicator revisions	April to July, 2015	USDA-OPMP USDA-APHIS USDA-FS
<i>Herbicide Resistance</i>		
Herbicide Resistance Internationally	March 16, 2015, seminar by Dr. Steve Powles, University of Western Australia	USDA-OPMP
Herbicide Resistance Management	September 24, 2015, with WSSA representatives October 23, 2015	USDA-OPMP USDA-APHIS-BRS
Herbicide Resistance Management Proposal	February 10, 2016, Weed Science Society of America	USDA – OPMP
	March 16, 2016, Federal IPM Coordinating Committee meeting	USDA-OPMP USDA-ARS USDA-NRCS USDA-NIFA USDA-NASS USDA-IR-4
<i>Methyl Bromide</i>		
Golden nematode – conference call to discuss alternatives for quarantine and control in Idaho	September 22, 2015	USDA-APHIS EPA – Region 10
<i>Outreach/Education</i>		
Iowa Crop Tour on herbicide resistant weeds	July 7 – 10, 2015	USDA-OPMP
Interagency Meeting on weed control issues	February 10, 2016	USDA- APHIS-BRS USDA - OPMP
Commodity Research & Opportunities Partnership (CROP) – representing corn, cotton, wheat,	October 8, 2015	USDA-OPMP

sorghum, and soybean growers		
Discussion with USDA on Sorghum-Johnsongrass Gene Flow Seminar & Persistence of Crop Alleles in the Weed Populations	September 9, 2015	USDA – APHIS – BRS
Webinar with Tribal Nations on Genetically Engineered crops	June 11, 2015	USDA-APHIS-BRS
Glyphosate resistance economics (webinar)	July 14, 2015	USDA-ERS
USDA Stakeholder Workshop on Coexistence – resistance management for biopesticides and herbicides	March 12 – 13, 2015	USDA-OPMP
Sulfonylurea herbicide meeting with registrants	April 1, 2015	USDA-OPMP
Golden nematode – conference call to discuss alternatives for quarantine and control in Idaho	September 22, 2015	USDA-APHIS EPA – Region 10

**Bost 3a.** Reliable data and analyses are critical to sound regulation. I have heard about a serious matter regarding EPA policies based on human research data that may not be reliable.

For years, EPA relied on hundreds of quality studies evaluating all aspects human susceptibility to pesticides called organophosphates. This included studies designed to make sure that children would be protected. Even though EPA used those high-quality assessments for 20 years the Agency now relies primarily on three epidemiology studies and some journal articles. Limiting the diversity of data creates a greater likelihood of inaccurate results. Why has EPA changed this process? Has limiting the number of studies increased the likelihood of inaccurate assessments? Was this change reviewed by a Scientific Advisory Panel? Was it subject to notice and public comment? Why is the Agency keeping this data from the public?

**EPA Response:** The EPA periodically reviews existing registered pesticides to ensure they can be used safely, without unreasonable risks to human health and the environment. The periodic review of pesticide registrations is required by FIFRA. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. The EPA will review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

As part of registration review, the EPA assesses any changes that have occurred since the last registration decision to determine whether the pesticide still satisfies the statutory standard for registration. The EPA considers any new data or information on the pesticide and decide whether a new risk assessment must be conducted. In the case of chlorpyrifos and the organophosphate pesticides, many of the epidemiology studies, mechanistic studies, and laboratory animal studies on the neurodevelopmental effects of organophosphate pesticides were published after reregistration was completed in 2006.

The EPA developed a "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" in 2010 which was reviewed by the FIFRA SAP and received public comment. The Panel commended the agency for developing the draft Framework and was "impressed with the documentation presented." The agency also notes that the Panel was supportive of the key components of the draft Framework, namely the use of problem formulation to assess data availability and quality early in the process and the modified Bradford Hill criteria as an internationally accepted tool for assessing epidemiology and laboratory animal data.

The agency has not limited the number of studies reviewed. In fact, the agency has reviewed hundreds of studies from laboratory animals, cell systems (including human), biomonitoring, and epidemiology on a variety of scientific areas related to human health effects. These studies were evaluated together in a weight of evidence analysis.

Therefore, there is significant new information relevant to the human health effects of organophosphate pesticides.

**Bost 3b.** I have recently been told that one of the studies that the EPA relies upon was conducted by Columbia University and that they have refused to provide the raw data to the Agency even though EPA partially funded the study. Is that true? At any point has EPA been allowed to review the raw data? Do you believe that its use is in compliance with the Administrative Procedures Act? How many times has this study been utilized for registrations and registration reviews? Was that study and its underlying data reviewed by a Scientific Advisory Panel? Was it subject to notice and public comment?

**EPA Response:** The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the federal courts have made clear that the EPA is not required by federal law to obtain or analyze the raw data in order to rely on such studies. The EPA therefore believes its consideration of these data is consistent with the Administrative Procedure Act. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

In the past, the EPA sought to obtain the original raw data used to support certain epidemiological analysis of *in utero* exposure to chlorpyrifos and subsequent adverse

neurodevelopmental health outcomes in children generated by the Columbia Center for Children's Environmental Health (CCCEH) to support the human health risk assessment of chlorpyrifos. Prior to the 2013 meeting with CCCEH investigators, the EPA thought these data would be important to both clarify the exposure-response relationship observed in the epidemiology study relative to the current regulatory endpoint (acetylcholinesterase inhibition), and also to resolve uncertainties regarding study participants co-exposure to other environmental contaminants, among other areas of uncertainties. CCCEH researchers did not agree to provide these data; however, the researchers met with the EPA and discussed the agency's questions about the data to help determine whether further review of the raw data might assist the EPA in resolving uncertainties. As a result of this meeting, the EPA concluded that access to the raw data would not provide answers to the EPA's questions. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, the EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties.

In the summer of 2015, the EPA made another attempt to obtain the raw data from Columbia University. The Columbia University investigators again denied the EPA's request. However, the investigators did provide additional summary information on the blood biomonitoring data. The agency has made this additional information publicly available.

Also in summer of 2015, Dr. Dana Barr of Emory University provided the agency with limited raw data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful the agency's current purpose of assessing risk to chlorpyrifos. The files provided from Dr. Barr do not contain the biomonitoring data from the key publications from CCCEH which describe associations between blood levels of chlorpyrifos and neurodevelopmental deficits in children. The agency has received two FOIA requests specifically asking for raw data on the three US children's cohorts. For the first FOIA request, EPA-HQ-2016-002089, the requester was provided all the responsive records (i.e., the files provided by Dr. Barr) and the request was closed March 2, 2016. For the second request, EPA-HQ-2016-003947, the agency did not have any additional files beyond those provided for the first request. The second FOIA was closed on March 22, 2016.

The agency has taken a stepwise, objective and transparent approach in evaluating, interpreting, and characterizing the strengths and uncertainties associated with all of the available lines of scientific information related to the human health effects of chlorpyrifos. This stepwise approach has included multiple reviews by the FIFRA SAP and other experts in addition to multiple opportunities for public comment.

The stepwise evaluation began with the September 2008 FIFRA SAP meeting involving a preliminary review of the literature for chlorpyrifos, with a particular focus on women and children (USEPA, 2008). In 2010, the EPA developed a draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which provides the foundation for evaluating multiple lines of scientific evidence, including epidemiology, in the context of the understanding of the adverse outcome pathway (or

mode of action (USEPA, 2010). The draft framework, which includes two key components: problem formulation and use of the modified Bradford Hill criteria, was reviewed favorably by the SAP in 2010 (FIFRA SAP, 2010). The EPA's draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization.

Because the SAP was basically supportive of the overall approach and the framework is consistent with recent, similar efforts by the WHO, the agency believes use of the draft framework in its current form is appropriate prior to the finalization of the document. The EPA used the draft framework for the 2014 chlorpyrifos revised risk assessment and the preliminary risk assessment for seven organophosphates in 2015. Currently, we are incorporating comments from the SAP and the public, and plan to finalize the framework in 2017.

In 2011, the agency released "Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review," focusing on the AChE inhibiting potential of chlorpyrifos (USEPA, 2011) and included assessment of exposures from dietary (food, water), occupational and residential pathways. The 2011 preliminary risk assessment was released for public comment. Also in 2011, the chlorpyrifos physiologically based pharmacokinetic-pharmacodynamic model (PBPK-PD) was reviewed by the FIFRA SAP (FIFRA SAP, 2011). [This model was used in the 2014 revised human health risk assessment described below.]

In 2012, the agency convened another meeting of the FIFRA SAP on chlorpyrifos which incorporated the newest experimental data related to AChE inhibition and both cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects (FIFRA SAP, 2012). Similarly, the agency also performed a more in-depth analysis of the biomonitoring data and of epidemiological studies from three major children's health epidemiology cohort studies in the U.S., as well as developed plausible hypotheses on MOAs/AOPs leading to neurodevelopmental outcomes (USEPA, 2012a). Following the 2012 SAP meeting, the agency solicited additional input from federal experts in the areas of Magnetic Resonance Imaging (MRI) and neurobehavioral testing in children to further clarify results obtained by examination of the epidemiological studies.

In December, 2014, the agency released "Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review" which went through public comment in 2015. Similarly, the agency's "Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides" was released for public comment in September, 2015.

The agency held another meeting of the FIFRA SAP in April 2016, to review a new analysis using the blood biomonitoring data from the Columbia University epidemiology study.

**Bost 3c.** It has also been brought to my attention that one of the authors of the study, Frederica Perera, Dr.P.H., Ph.D, of the Columbia University School of Public Health, is a member of the Board of Trustees of the Natural Resources Defense Council. The Natural Resources Defense Council has sued the EPA on a number of occasions to challenge pesticide registrations and often the supporting risk assessments. Has the EPA's Office of Inspector General been made aware of this conflict of interest? Has the Agency suspended use of the Columbia University epidemiology study in its risk assessment process until these concerns can be addressed?

**EPA Response:** While recipients of federal grants are subject to conflict of interest rules designed to insure that the competition for grants is fair and that the use of grant funds is appropriately managed, they are not otherwise subject to conflict of interest restrictions disqualifying them from eligibility to receive a grant based on affiliations with organizations that have sued the agency or supported particular regulatory activities. Accordingly, the EPA has not related this matter to the EPA Inspector General, nor has the EPA suspended its consideration of these data.

**Bost 3d.** If it is correct that EPA has not gotten access to that raw data, federal regulations designed to enhance the credibility of the federal rulemaking process have likely been violated. Data Quality Act violations and conflict of interest violations may have also occurred.

**EPA Response:** The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the federal courts have made clear that the EPA is not required by federal law, including federal rulemaking procedures, to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

The EPA's consideration of epidemiological data supporting the EPA's chlorpyrifos assessment is in keeping with the EPA's guidelines implementing the Information Quality Act. Those guidelines recognize that in some circumstances complete access to all methods and data cannot occur due to privacy, trade secrets, intellectual property, and other confidentiality protections. In those instances, EPA guidelines provide that the EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, the EPA should apply, to the extent practicable, relevant agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.

***Congressman Ralph Abraham, Louisiana***

**Abraham 1.** In response to my question about whether EPA treats herbicides used with crops improved through biotechnology differently than it treats all other herbicides, you stated that such herbicides “are not treated differently than looking at how we always look at pesticides, which is by the science trying to stick with the legal timelines and windows that we have to make our decisions.” . Furthermore, you indicated the agency is reducing the number of renegotiation extensions overall under the Pesticide Registration Improvement Act. Yet it is my understanding that EPA has consistently imposed disproportionate burdens and delays on registration activities related to biotechnology that it does not impose on similarly situated products that are not related to biotechnology.

Please provide this committee with examples of registration timelines, including all applicable registration renegotiations (the number of times a PRIA date was renegotiated and for how long) that support your statement that registrations tied to biotech traits are completed in the same general timeframe from submission to final label as registrations with no biotech crop application.

**EPA Response:** The EPA assesses risks and benefits for each pesticide registration application, striving to complete regulatory decisions within the timeframes designated under PRIA. The EPA employs the same process to review applications for herbicide uses on biotech crops as it does for other applications, identifying any risks of concern and conducting assessments to understand and address those risks. As with all applications, the EPA must address risk issues identified in the course of scientific review as well as comments received through the public participation process. Overall, the EPA has reduced the number of renegotiation extensions under PRIA. However, different chemicals and use patterns may present different risks, sometimes requiring more in depth and complex assessments to address them. More complex risks assessments may exceed average review timeframes in order to produce scientifically sound and legally defensible decisions.

The most complex reviews for new registration can involve the review and evaluation of requests to register pesticides for use on herbicide tolerant crops. While the number of applications in recent years are small, the review times range from approximately two years to approximately six years. These review times depend upon many factors, including any risk concerns identified and the time needed to negotiate risk mitigation strategies to address any potential unreasonable adverse effects, the need to wait to make a registration decision under FIFRA until other agencies make necessary safety findings under other relevant statutes, and the need to make the requisite findings under the Endangered Species Act.

An example of added complexity to a registration’s risk assessment for an herbicide use on herbicide tolerant crops is in the case of the Endangered Species Act. The EPA intends to complete endangered species assessments for new herbicide tolerant crop uses based on the Overview Document-compliant method. An assessment that is Overview Document-compliant follows the procedures and methods described in the Overview

Document (see [www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf](http://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf)). The EPA will complete these effect determinations as resources allow. To maximize impact within these limited resources, the initial registrations (e.g., Enlist Duo) are not nationwide in scope, and to the extent practical will focus on situations where EPA can make "no effect" decisions.

**Abraham 2.** Please provide this Committee with examples of registration decisions, other than those related to biotechnology, where EPA has intentionally delayed its approval until after another federal agency takes action on the crop associated with a pesticide's use pattern.

**EPA Response:** While we are not aware of any other actions where the EPA's decision rested on another federal agency taking action first, there have been circumstances where the EPA determined that consultation with another federal agency would improve the decision making for a particular registration application. The new active ingredient decision for the antibiotic kasugamycin is an example of a non-biotechnology registration decision in which the EPA consultation with other federal agencies was a contributing factor in the need to renegotiate the PRIA due date. To better understand the potential for bacterial resistance resulting from pesticidal use of the antibiotic, the EPA consulted with both the Centers for Disease Control and the Food and Drug Administration.

***Congressman David Rouzer, North Carolina***

**Rouzer 1.** EPA National Enforcement Initiatives. One of EPA's current enforcement initiatives for the fiscal years 2014-2016 expands enforcement action against our nation's animal agriculture operations. EPA is currently undergoing a process to modify the NEIs and this presents an opportunity that we support - returning this priority to the standard enforcement program - which is prudent considering the current NEI has not produced demonstrable water quality benefits. Administrator McCarthy, will you work to ensure that the new enforcement initiatives are based on sound science and demonstrated environmental benefits, rather than a doubling-down of efforts that have only acted to generate further distrust of EPA by America's farmers and ranchers?

**EPA Response:** The EPA identifies National Enforcement Initiatives based on public and stakeholder input, as well as extensive science-based analysis about public health threats from pollution. We recently announced the EPA's selection of the FY 2017-2019 National Enforcement Initiatives. Building on progress we've made from the current cycle of initiatives, the EPA determined that to protect American communities, it was important to retain its national initiative to prevent animal waste from contaminating surface and ground water. This will help focus important time and resources on protecting communities from improperly managed animal waste, which can result in water quality impairment, fish kills, algal blooms, contamination of drinking water sources, and transmission of disease-causing bacteria and parasites associated with food and waterborne diseases.

**Rouzer 2.** NPDES Electronic Reporting Rule. This rule (finalized by EPA on September 25, 2015) will result in EPA collecting farm information from states that goes beyond the

scope of the federal program. Taking into account EPA's accidental release of farm information to environmental activist groups in 2013, the lack of data security measures to prevent EPA from collecting non-NPDES farm information is very concerning to our nation's farmers and ranchers. Administrator McCarthy, can you ensure us that no superfluous information will be collected by the EPA through the electronic reporting rule?

**EPA Response:** The minimum set of NPDES program data that the EPA will collect through the NPDES Electronic Reporting Rule does not go beyond the scope of the federal program and is based on the EPA's current reporting requirements (see Appendix A to 40 CFR Part 127).

During the development of this rulemaking the EPA carefully considered input from authorized state programs, provided in comments and meetings, to match the minimum set of NPDES program data to the existing regulations and practice, including how these data are currently used by the EPA and authorized state programs. The EPA, in close collaboration with the states, streamlined the NPDES electronic reporting requirements down to the minimum number of data elements needed to oversee management of the NPDES programs in the most efficient manner possible. In particular, these data are necessary to properly identify potential sources of wastewater and stormwater pollution and to assess the effectiveness of authorized NPDES programs.

In particular, the EPA worked with authorized NPDES programs to ensure that the final rulemaking accurately captures EPA's existing Federal NPDES reporting requirements on Concentrated Animal Feeding Operations [e.g., 40 CFR Part 122.21(i)(1), 122.23, and 122.42(e)(4)]. Additionally, besides inspection information, authorized state programs are only required to share with the EPA data on facilities that are required to obtain NPDES permits under federal requirements.

**Rouzer 3.** Last September, the EPA published Interim Recommendations for environmental standards and ecolabels for use in federal procurement. EPA's recommendation for lumber excludes several credible standards that are widely used in the United States, including the Sustainable Forestry Initiative (SFI) and American Tree Farm System (ATFS) standards, which represent 70% of the certified acres in the U.S. EPA has signaled that this recommendation is mandatory for federal procurement. Under what circumstances may a federal procurement officer purchase wood products that do not meet this FSC requirement, such as those certified to SFI or ATFS? And, given the significant volume of sustainably harvested timber that is seemingly excluded from federal purchasing, please explain the process for EPA amending this recommendation in the future.

**EPA Response:** Under Executive Order 13693 - *Planning for Federal Sustainability in the Next Decade* – the EPA issued recommendations to assist federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A-119, and related federal policies that guide the EPA's use of voluntary consensus standards and private sector conformity assessment activities. In addition, the EPA continues to progress with piloting our Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement (the Guidelines), and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we develop these recommendations. The agency issued Federal Register Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.<sup>11</sup> Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations (FAR). As such, FAR Case 20 15-033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when it will be available to the public, are viewable at [http://www.acq.osd.mil/dpap/dars/far\\_case\\_status.html](http://www.acq.osd.mil/dpap/dars/far_case_status.html).

**Rouzer 4.** President Obama stated on January 21, 2009 that "The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails. . . . All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. The presumption of disclosure should be applied to all decisions involving FOIA."

However, on September 10, 2015, a federal district court opinion issued September 10, 2015, noted that EPA "continues to demonstrate a lack of respect for the Freedom of Information Act process . . . ." "The Court is left to wonder whether EPA has learned

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<sup>11</sup> Federal Register Notice, February 27, 2014, "Draft Guidelines for Product Environmental Performance Standards and Ecolabels for Voluntary Use in Federal Procurement" (79 FR 11102). <https://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04329.pdf>

Federal Register Notice, March 19, 2015, "Agency Information Collection Activities; Proposed Collection and Comment Request; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement" (80 FR 14372). <https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06275.pdf>

from its mistakes or if it will merely continue to address FOIA requests in the clumsy manner that has seemingly become its custom. Given the offensively unapologetic nature of EPA's recent withdrawal notice, the Court is not optimistic that the agency has learned anything."

In addition, a recent (January 2016) report of the House Committee on Oversight and Government Reform strongly criticized the failure of federal agencies to properly implement FOIA. Major problems included long delays and redacting information that should be made public. Improper redaction is a very serious "invisible" problem since FOIA requesters cannot determine if the agency is following the law. What specific steps will EPA undertake to do a better job in responding to FOIA requests?

Would you support legislation providing independent agencies – such as the Inspector General offices of the various Departments – the authority to confidentially sample FOIA responses and determine if the agency is improperly redacting material? In my view, that is likely to be the only way to determine if an agency is complying with the law regarding redactions.

**EPA Response:** The EPA takes its FOIA responsibilities seriously and is focused on creating more efficient work processes to ensure FOIA responses are prepared effectively and at lower cost. This includes adopting industry best practices for the delivery of information technology services in areas such as cloud computing, mobile technology and workplace standards. The EPA received close to 11,000 new FOIA requests in FY 2015 and successfully processed over 11,000 requests, reducing its FOIA backlog by several hundred requests.

The EPA also has improved its records management policies and procedures, including recent updates to the Records Management Policy ([http://www.epa.gov/records/policy/2155/rm\\_policy\\_cio\\_2155-3.pdf](http://www.epa.gov/records/policy/2155/rm_policy_cio_2155-3.pdf)) and new procedures to assist employees in the management of various types of electronic records. In addition, the agency's FOIA Expert Assistance Team was established in the fall of 2015. The team, part of the Office of General Counsel, is charged with overseeing and coordinating efforts on the agency's most complex FOIAs. The EPA has also deployed new technology tools, such as centralized searching and electronic review, to efficiently process large or complex requests.

The EPA already provides the Inspector General and Congress with information in non-redacted format upon request. In addition, the EPA has recently finalized the update of agencywide and office level FOIA procedures to clarify roles and responsibilities for responding to requests, including line by line review and limited redaction.

**Rouzer 5.** Americans are at an increasing threat from vector borne diseases. West Nile Virus and encephalitis have been serious problems for the last several years, but new diseases such as dengue fever and chikungunya are now an increasing threat to Americans and particularly infants. Sadly, new vector-born threats continue to emerge. In Mexico and South America, the mosquito-borne Zika virus is responsible for infants

being borne with significant birth defects. EPA is proposing very aggressive action to restrict the use of some critical mosquito control products. How is the Agency incorporating new public health threats into its risk assessments for products used in vector control?

**EPA Response:** The EPA is not currently proposing any actions to restrict the use of mosquito control products. The agency has recently released preliminary risk assessments that show risks of concern for some compounds; however, these are preliminary in nature and subject to change if additional data come to light. When refined risk assessments still show a concern, changes in use patterns or applications can sometimes be effective in mitigating the risk and allowing the compound to still be used in mosquito control.

When making a regulatory decision, the EPA considers the benefits (both public health and other) of these pesticides, along with their risks. The EPA consults with CDC when making a regulatory decision for any pesticide used to control a pest of public health significance. The EPA also frequently consults with other interested stakeholders to ensure that the agency has a complete picture of the benefits and have properly evaluated any proposed mitigation.

**Rouzer 6.** The federal rulemaking process includes very specific actions that a federal agency must take before promulgating new regulations. Some recent activities by the Office of Pesticide Program appear to circumvent the rulemaking process by sending pesticide registrants letters that outline new regulatory provisions. This “regulation by letter” procedure was used by EPA in 2013 to mandate registrants include pollinator statements and a graphic on certain pesticide products, and in 2009 for the Agency’s pyrethroid and pyrethrin labeling initiative. What is EPA’s rationale for circumventing the Administrative Procedure Act (APA), which includes notice and comment, economic and small business impact analysis, etc.? Will EPA provide the committee with assurances that it will abandon this policy of “regulation by letter” and instead follow the procedures and analysis required by the APA?

**EPA Response:** The EPA does not “regulate by letter” and FIFRA does not provide for such a regulatory mechanism to make changes to pesticide registrations. The EPA pesticide program is a licensing program that is based on an adjudicatory system. As a licensing program, the agency must ensure that the license complies with the law and continues to comply with the law. As such, decisions to grant a new license or change /modify an existing license are not subject to APA rulemaking, but the procedural requirements of FIFRA. When the EPA receives new information and determines that the license may lead to unreasonable adverse effects on the environment, the agency may offer the registrant a way to correct the imbalance in a timely manner. The August 2013 letter regarding labeling changes for the neonicotinoid insecticides is one example. However, if the registrant chooses not to address the concerns raised in such an offer, the agency can take appropriate steps under FIFRA to compel any necessary changes to the pesticide registration to mitigate unreasonable adverse effects on the environment. The letter itself is not self implementing; in the absence of voluntary agreement from a

registrant, FIFRA prescribes steps that the agency must take to impose new mitigation measures.

**Rouzer 7.** What farmers and communities in my district care about is the ability to defend against pest threats to their crops, food, homes and health. We have heard a lot today about what actions EPA has or is planning to take that impact the use of pesticides.

I believe it would be very helpful to this Committee for EPA to develop a comprehensive list of all the agency actions, and, not just rulemakings, during the last 8 years and those planned through the end of this year that restricted, or have the potential to restrict, existing or new uses of pesticides. Will you work with the Committee to determine what actions should be on that list so that Members can determine whether and how best to conduct appropriate oversight pursuant to our statutory obligations?

**EPA Response:** The EPA routinely provides opportunities for public comment on many pesticide regulatory actions. For example, before registering a new active ingredient or a significant new use of an already-registered active ingredient, the EPA engages stakeholders through its public participation process. Similarly, all registration review activities, including work plans, risk assessments, and proposed decisions, are the subject of public comment periods to ensure that stakeholders can provide the EPA with the highly quality information needed to make pesticide regulatory decisions.

The pesticide registration review process began in 2007 with the first decisions being made a few years later. To date, 165 decisions have been made. Of these decisions, 83 involved requests from the registrants to voluntarily cancel their registrations, in most cases for business decisions that were independent of the agency's review. For the remaining 82, many required no change to the registration or minor label clarification to make it easier for the user to understand and use the product correctly. Our anticipated registration review schedule can be found at [www.epa.gov/pesticide-reevaluation/registration-review-schedules](http://www.epa.gov/pesticide-reevaluation/registration-review-schedules).

During the same time period, the EPA has registered approximately 170 new pesticide active ingredients and more than 1,700 new uses of already registered active ingredients, providing numerous new products for use in agricultural and non-agricultural settings. These newly registered products are designed to address emerging pest pressures and will have a significant role in the marketplace.

Of these regulatory decisions to restrict or cancel certain registrations, the EPA made these decisions after careful consideration of all available data and consistent with existing statutory requirements. For example:

- In 2010, the EPA announced its decision to terminate all uses of endosulfan due to unacceptable risks to farmworkers and wildlife. The EPA signed a Memorandum of Agreement with the registrants of endosulfan that resulted in voluntary cancellation and provided for a phase-out of all existing endosulfan

uses in the United States in order to allow time for growers to transition to newer alternatives;

- In 2012, the EPA limited the use of chlorpyrifos by significantly lowering pesticide application rates and creating “no-spray” buffer zones around public spaces, including recreational areas and homes, due to concerns for unacceptable risks to children and bystanders;
- In 2014, the EPA cancelled propoxur pet collars. In the fall of 2013, the EPA completed the propoxur pet collar risk assessment. The EPA’s risk assessment indicated risks of concern to children from exposure to pet collars containing propoxur;
- In 2015, the EPA reached an agreement with Reckitt Benckiser, the manufacturer, to cancel all distribution of 12 consumer use d-CON products that did not meet the EPA’s current safety standards, raising concerns for risks to children and pets. Additionally, eight of the 12 products pose unacceptable risks to certain wildlife;
- In 2015, the EPA proposed to revoke all chlorpyrifos tolerances due to concerns with estimated exposure from drinking water in certain watersheds. A final tolerance rule is anticipated in March 2017;
- On November 24, 2015, while the issuance of the initial registration was being challenged in federal court, the EPA sought the remand and vacatur of the Enlist Duo registration because the EPA became aware of previously existing information about possible synergistic effects that had not been provided to the EPA or considered as part of the initial registration decision. The EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA;
- On July 2, 2013, the Pollinator Stewardship Council and others, petitioned for review of the sulfoxaflor registration in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion, finding that the registration was not supported by substantial evidence to demonstrate no unreasonable adverse effects to honey bees would result from the registration of sulfoxaflor. Although the initial sulfoxaflor submission contained all the data the EPA determined was necessary by the EPA for registration of a new agricultural insecticide, the Court vacated the registrations and remanded them to the EPA to “obtain further studies and data regarding the effects of sulfoxaflor on bees as required by EPA regulations.” The vacatur of the sulfoxaflor registrations became effective November 12, 2015. As the registrations were no longer in effect under FIFRA, on the same date the EPA issued a cancellation order to address existing stocks. Although the product registrations were vacated, the tolerances for sulfoxaflor residues on treated commodities that were established under the FFDCA, remain in place; and

- On March 4, 2016, the EPA issued a notice of intent to cancel the registration of four pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. The particular condition obligated the registrants to request cancellation if, after receiving additional required data, the EPA determined that use of flubendiamide did not meet the FIFRA standard for registration. Prior to issuing the notice, the EPA concluded that the continued use of flubendiamide will result in unreasonable adverse effects on the environment, particularly benthic invertebrates, which are an important part of the aquatic food chain, particularly for fish.

Over the past eight years, the EPA issued a number of regulations within the intention of providing clarity to the regulated community and other stakeholders or to update information that has become inaccurate or out of date. Examples of these rulemaking efforts include:

- **Minimum Risk** (Published 12/28/2015): This final rule more clearly describes the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. These changes maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and the EPA as to whether a product is in compliance with the exemption;
- **Crop Grouping** (Published Phase 1: 12/7/2007; Phase 2: 12/8/2010; Phase 3 8/22/2012; Phase 4: anticipated 2016): These final rules are likely to reduce the number of residue chemistry studies required to establish a tolerance for a crop within these crop groupings because instead of testing each crop individually, only the representative crops would need to be tested. Thus, the new crop groups ease the process for an entity to request and for the EPA to set pesticide tolerances on greater numbers of crops. Pesticides will be more widely available to growers for use on crops, particularly specialty crops;
- **Data Requirements for Antimicrobials (158W)** (Published 5/8/2013): the EPA revised the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practice, and to provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The EPA would use this information to conduct risk assessments for a particular pesticide;
- **Prions as Pests** (Published 2/28/2013): In 2003, the agency determined that a prion (proteinaceous infectious particles) is a "pest" under the FIFRA and that a product intended to reduce the infectivity of prions on inanimate surfaces (i.e., "prion product") is considered to be a pesticide. The EPA believes that regulating

prion-related products protects human health and the environment against unreasonable adverse effects and ensures that such products are effective;

- **Export Labeling** (Published 1/18/2013; Revisions Published 12/19/2014): The EPA revised the regulations pertaining to the labeling of pesticide products and devices that are intended solely for export. Pesticide products and devices intended solely for export are now able to meet the agency's export labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States. Collateral labeling ensures the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in, and consistent with the applicable requirements of the importing country; and
- **Data Compensation** (Published 2/5/2014): The EPA revised its regulations governing procedures for the satisfaction of data requirements under FIFRA, codified in 40 CFR part 152, subpart E. These provisions include, among other things, procedures for the protection of exclusive use and data compensation rights of data submitters. The EPA updated the regulations to accommodate statutory changes and changes in practice that have occurred since 1984; to make minor changes to clarify the regulations; and to make changes that would simplify the procedures and reduce burdens for certain data submitters. The revisions did not otherwise make substantive changes to the requirements.

At times, however, the EPA has determined that significant changes to its regulations are needed to improve public health. For example, in November 2015, the EPA finalized revisions to the Agricultural Worker Protection Standard. This final rule revised the federal regulations issued under FIFRA that direct agricultural worker protection (40 CFR 170). The changes reflected current research on how to mitigate occupational pesticide exposure to agricultural workers and pesticide handlers, and strengthened the protections provided to agricultural workers and handlers under the worker protection standard. The changes improved elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies, thus preventing exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. We are working closely with affected stakeholders, including state agricultural agencies, to ensure that they have the necessary information and training to implement these new protections.

Similarly, the EPA is now working to develop a final rule to revise the federal regulations governing the certified pesticide applicator program (40 CFR part 171). This action is intended to improve the competence of certified applicators of restricted use pesticides (RUPs) and to increase protection for noncertified applicators of RUPs operating under

the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators. State agricultural agencies, as well as many other stakeholders, provided valuable comments and suggestions in response to the EPA's proposed rule. We will work with stakeholders to ensure that the revised competency standards can be implemented effectively by state agencies.

***Congressman Rick Crawford, Arkansas***

**Crawford 1.** Then, we can take this as an example and a validation of the fact that the rulemaking process is deeply flawed, and needs to be addressed, because this kind of stuff, to me, is not reflective of the opportunity that should be granted to the affected stakeholders. Let me switch gears with you quickly in the time I have remaining. I was just told yesterday that the EPA took action against a farmer who didn't comply with the SPCC rules on on-farm fuel storage by failing to have an SPCC plan for his oil storage tank that was 5,000 gallons in size, but the 2014 WOTUS specifically says that EPA can only require compliance for oil storage tanks in excess of 6,000 gallons until such time as the EPA completes a study, and a new rulemaking process is undertaken.

My understanding is that the study is complete which recommends a lower exemption threshold, but the rulemaking is still not finished. So my question to you is why is the EPA taking enforcement action against individuals who are not out of compliance, and isn't that a violation of the law?

**EPA Response:** The EPA is are unaware of any situation such as the one described. The EPA respects the limits of its legal authorities as provided by law. The EPA's job is to assure compliance with the environmental laws as passed by Congress so that communities can be safeguarded from exposure to unhealthy pollutants and the environment can be protected.

***Congresswoman Ann Kuster, New Hampshire***

**Kuster 1.** Thank you, Mr. Chairman, and thank you to the Administrator for being with us today. Always great to have a New Englander in our Committee. I will be quick. I have 2 questions. The first one relates to this *Waters of the United States* rule, in conjunction with the EPA regulation on pesticides, and the Fish and Wildlife ruling regarding the long-eared bat. And my question on behalf of farmers, landowners, and timber owners in New Hampshire is how will your agency coordinate with USDA and Fish and Wildlife to minimize confusion about the interplay between these three rules? If you follow.

**EPA Response:** The Clean Water Rule does not itself establish any new requirements regarding either the use of pesticides or compliance with the Endangered Species Act. As a result, issuance of the Clean Water Rule does not change current requirements regarding application of pesticides to waterbodies or provisions of the ESA, including provisions associated with listing of the Long Eared Bat. New Hampshire is one of the four states where the Pesticide General Permit (PGP) applies statewide. The EPA coordinated closely with USDA on the development of the 2011 permit. The EPA continues to coordinate closely with USDA and is currently consulting with the NMFS

and FWS in the development and reissuance of the 2016 PGP. Consideration of relevant endangered or threatened species will occur during that consultation.

***Congressman Doug LaMalfa, California***

**LaMalfa 1.** On the issue of Section 404, and the exemptions that are provided for agriculture under the Clean Water Act, normal farming activities, ranching, forestry, *ecetera*, including repeat plowing, seeding, cultivating, minor drainage, harvesting for that production of the food and the fiber and forest products, conservation practices, *et cetera*, no additional requirements, for example, that an activity be continuous are included.

Some of my constituents are continuous cropping on these lands, otherwise you lose your ability to have that exemption. Nowhere in the law does it specify that, but that is what is being carried out in my district by EPA or your associates. Sometimes we refer to them as henchmen, but in the Army Corps of Engineers that are carrying out some very outside the law activities with this regulation. So do you agree that Section 404 does make no additional requirements that an activity be a continuous crop, as we see it in the law?

**EPA Response:** When Congress enacted CWA Section 404(f) in 1978, the statute included the term “normal” to characterize farming, ranching, and forestry practices covered by the exemption. “Normal” farming, ranching, and forestry practices are those that are established or ongoing. The agencies have not interpreted “normal” to mean “continuous” but rather that farming, ranching, or forestry has been previously established and ongoing on the property. If lands are left fallow, for example, as part of crop rotation or to rest soils, such lands remain subject to the exemptions. The agencies are always glad to answer landowner questions regarding the 404(f) exemptions and to help landowners conduct their activities in waters consistent with the statute.

**LaMalfa 2.** Appreciate your time, and your grace with which you have answered the questions today. Just to bring your attention quickly, a Presidential memorandum recently issued, it is called *The Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments*. I don't expect you to know this, and not to put you on the spot here, but, again, *Mitigating Impacts on Natural Resources from Development, and Encouraging Related Private Investments*.

It is a fairly new Presidential memorandum.

It appears to be carrying the weight of an Executive Order, and seems like quite a significant departure from current policy. Looking like it is going to go back and reassess every possible impact that a man made activity might have on public land, or any natural resource on Federal projects. So do you plan to follow this policy, and can you walk me through, in a letter later on, how you do plan—are you aware of that title?

**EPA Response:** The Presidential Memorandum, “Mitigating Impacts on Natural Resources from Development and Encouraging Related Private Investment,” was issued

on November 3, 2015, and applies to the Departments of the Interior, Defense, and Agriculture and to the EPA and NOAA. A key goal of the Memorandum is to “increase private investment in natural resource restoration” and to accomplish this by ensuring that “[f]ederal policies are clear, work similarly across agencies, and are implemented consistently across agencies.” Section 1 calls on agencies to “adopt a clear and consistent approach for avoidance and minimization of, and compensatory mitigation for, the impacts of their activities and the projects they approve.” Clear policies with respect to mitigation are expected to offer opportunities for increasing private investment in natural resource restoration. General “principles” guiding this effort are defined in section 3, and section 4 calls on selected agencies to review and update specific manuals, handbooks, and policies. As indicated in section 5(b), the Memorandum is to be “implemented consistent with applicable law.”

***Congressman Dan Benishek, Michigan***

**Benishek 1.** Last September the EPA published an interim recommendation for environmental standards and eco labels for use in Federal procurement. And one of the recommendations for lumber excludes several credible standards that are widely used in the United States, including the Sustainable Forest Initiative, and the American Tree Farmer System standards. And we understand that this recommendation was made without consultation with the Department of Agriculture, who not only have a lot of expertise in forest management and forest projects, but who also publicly stated that the Sustainable Forest Initiative, and the American Tree Farmer System standards can be used to verify sustainability of forest products. Furthermore, it is supposedly based on a determination by the Department of Energy that has no formal analysis behind it. So can you explain the basis of this recommendation for Federal procurement? Why wouldn't you consult with the Department of Agriculture prior to making this kind of a rule?

**EPA Response:** Under Executive Order 13693 - *Planning for Federal Sustainability in the Next Decade* – the EPA issued recommendations to assist federal purchasers in identifying and procuring environmentally sustainable products. The EPA's Interim Recommendation for the lumber/wood category is based on the Department of Energy's Fiscal Year 2016 (FY16) Priority Products List.

As a result of stakeholder inquiries since the release of the Interim Recommendation, the EPA has met and is continuing to work with USDA and DOE's Office of Sustainable Environmental Stewardship to gain further information. The EPA's Standards Executive is reaching out to the Sustainable Forestry Initiative, the American Tree Farm System, and the other forestry labels that stakeholders have requested the EPA consider. The EPA will be in touch with these groups regarding the agency's review of forestry labels and their alignment with the National Technology Transfer and Advancement Act, the OMB Circular A-119, and related federal policies that guide the EPA's use of voluntary consensus standards and private sector conformity assessment activities. In addition, the EPA continues its progress with piloting the Guidelines for Assessing Standards and Ecolabels for Use in Federal Procurement, and hopes that information gleaned from this process will inform thinking related to the lumber/wood category. Finally, DOE

continues to conduct research to inform their FY16 Priority Products List. The EPA looks forward to reviewing all of this additional data to inform if and how the lumber/wood category of Interim Recommendations might be revised.

The EPA has, and will continue to provide, mechanisms for public input as we develop these recommendations. The agency issued Federal Register Notices on the initial draft guidelines in 2014 and in March 2015 for the launch of our pilot work.<sup>12</sup> Those FRNs were open to public comment and they marked the beginning of our efforts to engage multi-stakeholder panels whose counsel will be considered as we move to finalize our recommendations. Further, any federal acquisition requirements stemming from the recommendations would include a public comment process prior to incorporation into the Federal Acquisition Regulations. As such, FAR Case 20 15-033 has been developed in order to integrate the new requirements of E.O. 13693 into the FAR. All next steps related to this case, including as to when it will be available to the public, are viewable at [http://www.acq.osd.mil/dpap/dars/far\\_case\\_status.html](http://www.acq.osd.mil/dpap/dars/far_case_status.html).

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